OAH Docket No. 15-0900-19846-1
Governor's Tracking No. AR 070

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE DEPARTMENT OF HEALTH

In the Matter of the Proposed Rules Governing Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717.

REPORT OF THE ADMINISTRATIVE LAW JUDGE

Administrative Law Judge ("ALJ") Beverly Jones Heydinger conducted a hearing concerning the above-entitled rules proposed by the Minnesota Department of Health ("Department" or "MDH") on October 10, 2008, at the Freeman Building, 625 Robert Street North, Saint Paul, Minnesota. The hearing continued until everyone present had an opportunity to state his or her views on the proposed rules.

The hearing and this Report are part of a rulemaking process governed by the Minnesota Administrative Procedure Act.[1] The legislature has designed the rulemaking process to ensure that state agencies have met all the requirements that Minnesota law specifies for adopting rules. Those requirements include assurances that the proposed rules are necessary and reasonable and that any modifications that the agency made after the proposed rules were initially published do not result in the rules' being substantially different from what the agency originally proposed. The rulemaking process also includes a hearing when a sufficient number of persons request one. The hearing is intended to allow the agency and the Administrative Law Judge reviewing the proposed rules to hear public comment regarding the impact of the proposed rules and what changes might be appropriate.

The members of the Department's hearing panel were Patricia Winget, Attorney, Rulemaking Coordinator; Paul Moyer, Environmental Research Scientist, Project Director; Helen Goeden, Ph.D., Senior Toxologist; Christopher Greene, Research Scientist; and Iman Hassan, Research Scientist. Twenty-three members of the public signed the hearing register.

The Department and the Administrative Law Judge received written comments on the proposed rules prior to the hearing. At the hearing, the initial deadline for filing written comment was set at twenty calendar days (October 30, 2008), to allow interested persons and the Department an opportunity to submit written comments. Following the initial comment period, the record remained open for an additional five business days (November 6, 2008), to allow interested persons and the MDH the

[1] Minn. Stat. §§ 14.131 through 14.20. (Unless otherwise specified, all references to Minnesota Statutes are to the 2008 edition, and all references to Minnesota Rules are to the 2007 edition.)

opportunity to file a written response to the comments received during the initial period. To aid the public in participating in this matter, comments were posted on the Office of Administrative Hearings' website as they were received. Numerous comments were received during the rulemaking process. The hearing record closed for all purposes on November 6, 2008.

NOTICE

The Department must make this Report available for review by anyone who wishes to review it for at least five working days before the Department takes any further action to adopt final rules or to modify or withdraw the proposed rules. If the Department makes changes in the rules other than those recommended in this report, it must submit the rules, along with the complete hearing record, to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

Because the Administrative Law Judge has determined that the proposed rules are defective in certain respects, state law requires that this Report be submitted to the Chief Administrative Law Judge for his approval. If the Chief Administrative Law Judge approves the adverse findings contained in this Report, he will advise the Department of actions that will correct the defects, and the Department may not adopt the rules until the Chief Administrative Law Judge determines that the defects have been corrected. However, if the Chief Administrative Law Judge identifies defects that relate to the issues of need or reasonableness, the Department may either adopt the actions suggested by the Chief Administrative Law Judge to cure the defects or, in the alternative, submit the proposed rules to the Legislative Coordinating Commission for the Commission's advice and comment. The Department may not adopt the rules until it has received and considered the advice of the Commission. However, the Department is not required to wait for the Commission's advice for more than 60 days after the Commission has received the Department's submission.

If the Department elects to adopt the actions suggested by the Chief Administrative Law Judge and make no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, it may proceed to adopt the rules. If the Department makes changes in the rules other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, it must submit copies of the rules showing its changes, the rules as initially proposed, and the proposed order adopting the rules to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

After adopting the final version of the rules, the Department must submit them to the Revisor of Statutes for a review of their form. If the Revisor of Statutes approves the form of the rules, the Revisor will submit certified copies to the Administrative Law Judge, who will then review them and file them with the Secretary of State. When they are filed with the Secretary of State, the Administrative Law Judge will notify the Department, and the Department will notify those persons who requested to be informed of their filing.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

I. Background and Nature of the Proposed Rules

A. Overall Purpose

1. The revised rules establish methods for calculating health-protective limits, called "Health Risk Limits" (HRLs), for contaminants in groundwater; apply that formula to calculate HRLs for individual chemicals, taking into account statutory directives; and establish a procedure for assessing risk from multiple chemicals in combination.

As MDH states in its Statement of Need and Reasonableness (SONAR):

> [t]he most significant changes in this revision represent a concerted effort to ensure that the process used for deriving HRLs incorporates provisions necessary to protect sensitive or highly exposed populations. This reflects not only MDH's mission to protect the health of all Minnesotans, but also the mandate in the 2001 Health Standards Statute that safe drinking water standards include 'a reasonable margin of safety to adequately protect the health of infants, children, and adults….'[2]

2. Because groundwater is a potential source of drinking water for all Minnesotans, in developing its revisions, MDH has considered that personal and demographic characteristics and behaviors may make some individuals or groups more vulnerable to harm from contaminants in drinking water because they drink more water or have pre-existing health conditions and that infants and children may be more vulnerable than adults because of their body weight and ingestion rates. MDH also considered that at certain life stages, such as organ development, people may be more sensitive to toxic effects than at other life stages. Although the SONAR cannot be fully summarized in this report, it provides a detailed, extensive explanation of the rationale for the proposed rule revisions and the process MDH followed to develop the revisions.

B. Need for the Proposed Revisions

3. MDH has offered several reasons for pursuing revision of its rules at this time. Since the last broad revision of the health risk limits in 1992 and 1994, additional contaminants have been detected in Minnesota's groundwater; more toxicological research has been conducted; risk assessment methods and guidelines have advanced; there is increased concern about the effect of chemicals on children; and the Legislature established a 2009 deadline for updating the acceptable levels of the most

[2] Statement of Need and Reasonableness (SONAR) at 1, citing Minn. Stat. § 144.0751.

commonly identified groundwater contaminants.[3] Moreover, in 2001, the Minnesota Legislature directed that new or revised drinking water and air quality standards:

> ….include a reasonable margin of safety to adequately protect the health of infants, children, and adults by taking into consideration risks to each of the following health outcomes: reproductive development and function, respiratory function, immunologic suppression or hypersensitization, development of the brain and nervous system, endocrine (hormonal) function, cancer, general infant and child development, and any other important health outcomes identified by the commissioner.[4]

4. In 2001, MDH announced its intention to review the risk assessment principles underlying these rules. Since that time, it has engaged in a lengthy process to reexamine its principles, review new research and guidance from the U.S. Environmental Protection Agency (EPA), develop proposals, seek independent peer review, solicit comments, and provide public information about the proposed revisions.[5] The results are these proposed amendments to the rules.

5. By statute, an HRL is defined as: "a concentration of a substance or chemical adopted by rule of the commissioner of health that is a potential drinking water contaminant because of a systemic or carcinogenic toxicological result from consumption."[6] This definition is incorporated in the proposed rule, which clarifies that the HRL is expressed as "micrograms per liter (µg/L)".[7]

6. There is further discussion of an HRL in the SONAR. An HRL is "the concentration of a chemical in drinking water that, based on the current level of scientific understanding, is likely to pose little or no health risk to humans, including vulnerable subpopulations."[8] It is a function of: how toxic a chemical is, the duration of exposure to it, and the amount of water individuals drink during the exposure period. An HRL value also incorporates adjustments to account for uncertainty about a chemical's health risks, with a higher degree of conservatism built into the HRL to reflect higher degrees of uncertainty.

C. General Description of the Process to Set HRLs

7. Portions of the process to set HRLs will be discussed in greater depth below, as related to specific rule provisions. However, in order to introduce the relevant terms and process, it is helpful to provide a brief overall introduction.

---

[3] Minn. Laws 2007, Ch. 147, Art. 17, § 2. *See also* SONAR at 17-20.
[4] Minn. Stat. § 144.0751 (a)(1).
[5] SONAR at 15-16.
[6] Minn. Stat. § 103H.005, subd. 3.
[7] Minn. R. 4717.7820, subp. 13 (proposed).
[8] SONAR at 2.

8. The accepted method for assessing potential toxicity to humans is through controlled laboratory studies using mammals. The testing has two goals: first, to identify the hazard or toxic effects caused by the chemical; and second, to evaluate the relationship between the dose and the animal's response. Researchers attempt to determine the lowest dose at which adverse effects related to dosing are observed (the "lowest observed adverse effect level," or LOAEL), and the highest dose at which no adverse effects related to dosing are observed (the "no observed adverse effect level," or NOAEL).

9. For noncancer effects, the selected dose is reduced to account for variability and uncertainty in the human population. In some instances the variability and uncertainty are so great that there is insufficient scientific information available to calculate a "reference dose" (RfD), that is, the milligrams of chemical per kilogram of body weight per day (mg/kg-day) that is estimated to be without an appreciable risk of adverse effects.[9] Where sufficient information was available, MDH considered the timing and duration of exposure to determine acute, short-term, subchronic, and chronic RfDs.

10. For carcinogens, that is, chemicals that cause cancer, most HRLs employ the "default assumption" that any amount of exposure, no matter how small, potentially carries some risk. Rather than developing a reference dose for carcinogens, MDH incorporated its long-standing policy to derive values that limit the excess cancer risk to 1 in 100,000, that is the level that increases the incidence of cancer by 1 in 100,000 population.

D. 2007 Legislation

11. In 2007, the Minnesota Legislature recognized the need to update the HRLs and the methods used to derive them. It directed that the Department establish HRLs for all contaminants in private domestic wells to be the more stringent of either the state standards (*i.e.*, HRLs) or the federal standards determined by EPA (*i.e.* Maximum Contaminant Levels, MCLs).[10] Based on this directive, MDH adopted MCL-based HRLs for eleven chemicals, effective July 1, 2007, and published those values in the State Register.[11] Those values will remain in effect until MDH derives and promulgates revised values for those chemicals. In this revision of the rules, MDH applies its proposed algorithm and proposes HRLs for three of the eleven chemicals (alachlor, benzene and 1,1,1-trichloroethane), replacing the MCLs for those three chemicals. MDH has included the MCL-based HRL values for the remaining eight chemicals[12] in this revision of the rules and proposes that those values remain in effect until it develops

[9] SONAR at 3.

[10] Minn. Laws 2007, Ch. 147, Art. 17, § 2.

[11] 32 State Register 43 (July 9, 2007).

[12] Atrazine, di-(2-ethylhexyl) phthalate), dichloromethane, pentachlorophenol, simazine, tetrachloroethylene, 1,1,2-trichloroethylene, and 2(2,4,5-trichlorophenoxy)propionic acid.

new HRL values in future rule revisions. In addition, MDH has adopted the MCL for nitrate as its HRL until it completes its own review of that chemical.[13]

12. The same legislation directed MDH to identify the most commonly detected contaminants in groundwater and to adopt HRL rules for ten commonly detected contaminants by March 1, 2009. MDH consulted with other agencies and collaborated to classify commonly detected chemicals into priority categories. Through that process, thirteen chemicals were ranked "high," based on frequency of detection and significance as a groundwater contaminant.

13. Of the thirteen chemicals in that group, MCL-based HRLs are in effect for four; a fifth, nitrate, is included in this rule revision as an MCL-based HRL.[14] The additional eight high-ranked chemicals are also covered by these rules. There are MDH-derived HRLs for five additional "high" ranked chemicals, three newly proposed and two currently included in MDH's temporary rule, as discussed below. The three newly developed HRLs for "high" ranked chemicals are for: cis 1,2-dichloroethylene, benzene, and vinyl chloride.

14. Two additional "high" ranked chemicals, deethylatrazine and deisopropylatrazine, are addressed in the revised rules by a new provision, Part 4717.7900, which deals with chemical breakdown products.[15]

15. In 2007, the Legislature directed MDH to derive and adopt by rule HRLs for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) by August 1, 2007.[16] As authorized, MDH adopted a temporary rule, and it has included its HRL values for PFOA and PFOS in these permanent rule revisions.[17]

16. In addition to the thirteen high-ranked contaminants, and four additional chemicals with MCLs, the rules set new HRLs for five additional chemicals: acetochlor, chloroform, cyanazine, dieldrin and 1,3,5-trimethylbenzene. Thus, the proposed rules set limits for 21 chemicals.[18]

II. Compliance with Procedural Rulemaking Requirements

17. On September 10, 2007, the MDH published in the State Register its Request for Comments on the Department's possible amendments of rules governing health risk limits for groundwater. The notice indicated that a draft of the proposed rules would be available and requested comments on the proposed language.[19] The

[13] SONAR at 10-13.
[14] SONAR at 12-13.
[15] SONAR at 12-13.
[16] Minn. Laws 2007, Ch. 37.
[17] SONAR at 12.
[18] One additional HRL was withdrawn prior to hearing.
[19] 32 State Register 467 (September 10, 2007); Ex. 1.

Department also published a Request for Comments on September 24, 2001,[20] and December 27, 2004.[21]

18. As required by Minn. Stat. § 14.131, the Department asked the Commissioner of the Department of Finance to evaluate the fiscal impact and benefit of the proposed rules on local units of government. The Department of Finance provided comments in a memorandum dated July 24, 2008.[22]

19. On August 7, 2008, the MDH filed copies of the proposed Notice of Hearing, proposed rules, and draft SONAR with the Office of Administrative Hearings. The filings complied with Minn. R. 1400.2080, subp. 5.[23] On the same date, the MDH also filed a proposed additional notice plan for its Notice of Hearing and requested that the plan be approved pursuant to Minn. R. 1400.2060. By letter of August 14, 2008, the Administrative Law Judge approved the additional notice plan and the Notice of Hearing.

20. On August 28, 2008, the Department mailed the Notice of Hearing to all persons and associations who had registered their names with the MDH for the purpose of receiving such notice.[24] The Notice contained the elements required by Minn. R. 1400.2080, subp. 2. The Notice identified the date and location of the hearing in this matter. The Notice also announced that the hearing would continue until all interested persons had been heard.

21. On August 28, 2008, the Department sent a copy of the Notice of Hearing and SONAR to the legislators specified in Minn. Stat. § 14.116.[25]

22. Also on August 28, 2008, the Department mailed a copy of the SONAR to the Legislative Reference Library.[26]

23. On September 2, 2008, the proposed rule and the Notice of Hearing were published in the State Register.[27]

24. At the hearing, the MDH filed copies of the following documents as required by Minn. R. 1400.2220:

[20] 26 State Register 462 (September 24, 2001); Ex. 1.
[21] 29 State Register 765 (December 27, 2004); Ex. 1.
[22] Ex. 11.
[23] Letter from Paul Moyer dated August 6, 2008.
[24] Ex. 7.
[25] Ex. 11.
[26] Ex. 5.
[27] 33 State Register 418 (September 2, 2008); Ex. 6.

A. the three Requests for Comments as published in the State Register on September 10, 2007 (32 S.R. 467), December 27, 2004 (29 S.R. 765), and September 24, 2001 (26 S.R. 462);[28]

B. the proposed rules dated July 1, 2008, including the Revisor's approval;[29]

C. the Statement of Need and Reasonableness (SONAR);[30]

D. the Certificate of Mailing the SONAR to the Legislative Reference Library on August 28, 2008, including the cover letter;[31]

E. the Notice of Hearing as published in the State Register on September 2, 2008 (33 S.R. 418);[32]

F. the Certificate of Mailing the Notice of Hearing to the Rulemaking Mailing List on August 28, 2008, and the Certificate of Accuracy of the Mailing List;[33]

G. the Certificate of Giving Additional Notice Pursuant to the Additional Notice Plan on September 2, 2008;[34]

H. public comments received by the Department prior to the hearing;[35]

I. other relevant documentation, including: curriculum vitae for Melanie A. Marty, Ph.D.; curriculum vitae for John L. Adgate, Ph.D.; documentation demonstrating that the Department consulted with the Commissioner of Finance; the Certificate of Sending the Notice and the SONAR to Legislators on August 28, 2008, accompanied by a copy of the transmittal letter; the August 2008 Minnesota Department of Health Fact Sheet regarding the proposed rules; and legislation relevant to the 2008 Health Risk Limits for Groundwater Rules Revision;[36]

J. Health Risk Limits for Groundwater: 2008 Rules Revision Summary power point presentation;[37]

---

[28] Ex. 1. Ex. 2 indicates that there was no petition for rulemaking applicable to this rulemaking.
[29] Ex. 3.
[30] Ex. 4.
[31] Ex. 5.
[32] Ex. 6.
[33] Ex. 7.
[34] Ex. 8.
[35] Ex. 9. Ex. 10 indicates that the Department did not seek authorization from OAH to omit a copy of the rules from the State Register because it in fact published the text.
[36] Ex. 11.
[37] Ex. 12.

K. written comments by James Sherman, Ph.D., DABT, on behalf of Monsanto Company;[38]

L. written comments from the American Chemistry Council and Rick Becker; and[39]

M. written comments from Kathleen Schuler on behalf of the Institute of Agriculture and Trade Policy.[40]

25. With one exception, the Administrative Law Judge finds that the Department has submitted all of the documents required by Minn. R. 1400.2220.

26. Minn. R. 1400.2220 describes the documents that must be placed into the hearing record at the rule hearing. Item F requires an agency to submit "the notice of hearing or dual notice as mailed and as published in the State Register." In this case, the Department submitted the Notice of Hearing as published in the State Register but not the Notice of Hearing as it was mailed to interested parties.[41]

27. In this instance, the Administrative Law Judge finds the Department's failure to submit the Notice of Hearing as mailed is harmless error under Minn. Stat. § 14.15, subd. 5, because this omission did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process. The record clearly demonstrates that the Department mailed the Notice of Hearing to its rulemaking mailing list.[42]

III. Statutory Authority

28. In its SONAR, the Department asserts that its statutory authority to adopt rules regarding HRLs for groundwater is contained in Minn. Stat. §§ 103H.201, subd. 1 (a), (c), and (d) and 144.0751; Minnesota Session Laws 2007, Chapter 37; and Minnesota Session Laws 2007, Chapter 147, Article 17, Section 2.[43]

29. The Groundwater Protection Act of 1989 is codified in Minnesota Statutes, Chapter 103H. The relevant portions of Minn. Stat. § 103H.201, subd. 1, provide as follows:

> (a) If groundwater quality monitoring results show that there is a degradation of groundwater, the commissioner of health may promulgate health risk limits under subdivision 2 for substances degrading the groundwater.

---

[38] Ex. 13.
[39] EX. 14.
[40] Ex. 15.
[41] *See* Ex. 6.
[42] *See* Ex. 7.
[43] SONAR at 11-12.

(c) For systemic toxicants that are not carcinogens, the adopted health risk limits shall be derived using United States Environmental Protection Agency risk assessment methods using a reference dose, a drinking water equivalent, and a relative source contribution factor.

(d) For toxicants that are known or probable carcinogens, the adopted health risk limits shall be derived from a quantitative estimate of the chemical's carcinogenic potency published by the United States Environmental Protection Agency and determined by the commissioner to have undergone thorough scientific review.

30. The Health Standards Statute of 2001 is codified in Minnesota Statutes, Chapter 144. The Department indicates that additional authority is implicit in Minn. Stat. § 144.0751, which applies to "safe drinking water or air quality standards established or revised by the commissioner of health." This statute provides, in part:

(a) Safe drinking water or air quality standards established or revised by the commissioner of health must:

(1) be based on scientifically acceptable, peer-reviewed information; and (2) include a reasonable margin of safety to adequately protect the health of infants, children, and adults by taking into consideration risks to each of the following health outcomes: reproductive development and function, respiratory function, immunologic suppression or hypersensitization, development of the brain and nervous system, endocrine (hormonal) function, cancer, general infant and child development, and any other important health outcomes identified by the commissioner.

31. The Department argues that Minn. Stat. § 144.0751 gives it the necessary authority to revise the proposed rules to incorporate both science-based and policy-based protections for sensitive populations, including infants and children.

32. In addition, the Department cites the good cause exempt rulemaking that it completed in 2007 regarding HRLs for PFOA and PFOS. The HRLs established for PFOA and PFOS in that rulemaking were only valid for two years under Minn. Stat. § 14.388, and the Department now seeks to make those values permanent in the current rulemaking.[44]

33. Finally, Minnesota Session Laws 2007, Chapter 147, Article 17, Section 2 provides the following regarding water level standards:

(a) Until the commissioner of health adopts rules setting the health risk limits required in paragraph (b), the health risk limit for all contaminants in private domestic wells must be the more stringent of the state

[44] SONAR at 12.

standards or the federal standards determined by the United States Environmental Protection Agency.

(b) By March 1, 2008, the commissioner of health must publish in the State Register notice of intent to adopt rules relating to health risk limits for commonly detected contaminants. The commissioner of health shall review current scientific information to establish health risk limits for commonly detected contaminants in groundwater that provides a reasonable margin of safety to adequately protect the health of developing fetuses, infants, and children, in accordance with the requirements of Minnesota Statutes, section 144.0751. Nothing in paragraph (a) prohibits the commissioner from setting standards that are stricter than the federal standards.

(c) By March 1, 2009, the commissioner shall adopt rules relating to health risk limits for the ten most commonly detected contaminants.

(d) By February 1, 2008, the commissioner shall report to the legislature on the implications for public health and the costs to enforce the more stringent of health risk limits or maximum contaminant levels for public water systems.

34. It should be noted that the Department did not publish its notice of intent to adopt rules relating to health risk limits for commonly detected contaminants until September 2, 2008.[45] But, there is a well-established rule of statutory construction that statutory provisions defining the time and mode in which public officers shall discharge their duties, and which are obviously designed merely to secure order, uniformity, system, and dispatch in public business, are generally deemed to be directory (as opposed to mandatory) in nature.[46] While public agencies should make every effort to comply with directory time periods, their failure to do so does not deprive them of the authority to engage in subsequent action where the statute does not specify any consequences for their failure to act.[47]

---

[45] Ex. 6.

[46] *Heller v. Wolner*, 269 N.W.2d 31, 33 (Minn. 1978), *citing, Wenger v. Wenger*, 200 Minn. 436, 438, 274 N.W. 517, 518 (1937) (Failure to hold hearing within 30-day statutory time period did not deprive court of jurisdiction where the statute does not provide any consequences to the parties for the court's failure to act.)

[47] *Id. See also Henry v. Minnesota Public Utilities Commission*, 392 N.W.2d 209 (Minn. 1986) (failure of MPUC to issue a decision in a rate proceeding within 10-month suspension period did not deprive MPUC jurisdiction to issue decision); *First National Bank of Shakopee v. Department of Commerce*, 245 N.W.2d 861 (Minn. 1976) (statute requiring Department of Commerce to issue its decision within 90 days of hearing on bank application, is directory only, and violation of 90-day requirement did not invalidate Commissioner's subsequent order); *Szczech v. Commissioner of Public Safety*, 343 N.W.2d 305 (Minn. App. 1984) (defining "shall" as mandatory in Minn. Stat. § 645.44(16) is only a rule of construction and is not binding on the courts).

35. The Department is clearly on track to adopt these proposed rules by March 1, 2009, as directed by the legislature. Minnesota Session Laws 2007, chapter 147, article 17, section 2 is directory in nature and does not specify any penalty for the failure of the MDH to publish its notice of intent by March 1, 2008. A violation of a directory statute does not invalidate the subsequent action taken.[48] Furthermore, the deadline to publish the notice of intent imposed by the legislature falls well short of the 18-month time limit imposed by Minn. Stat. § 14.125. By publishing its notice of intent by September 2, 2008, the Department was well within the time limit required by Minn. Stat. §14.125. The Administrative Law Judge concludes that the failure of the MDH to meet the legislature's directive to publish notice of intent to adopt rules by March 1, 2008, does not deprive the Department of statutory authority to proceed with this rulemaking.[49]

36. The Administrative Law Judge finds that the Department has specific and general statutory authority to adopt the proposed rules.

IV. Additional Notice Requirements

37. Minn. Stat. §§ 14.131 and 14.23 requires that an agency include in its SONAR a description of its efforts to provide additional notification to persons or classes of persons who may be affected by the proposed rule or explain why these efforts were not made. As discussed above, the Department submitted an additional notice plan to the Office of Administrative Hearings, which was reviewed and approved by the Administrative Law Judge in a letter dated August 14, 2008. During the rulemaking hearing, the MDH introduced evidence that certified provision of notice to those on the rulemaking mailing list maintained by the MDH and in accordance with its additional notice plan.[50]

38. A copy of the proposed rules, the Notice of Hearing, and the SONAR were all available on the Department's website. The Department also posted notices of public meetings, summaries of all public meetings, summaries of science and policy recommendations by MDH research scientists, and summaries of toxicological findings for each chemical.[51]

---

[48] *City of Chanhassen v. Carver County*, 369 N.W.2d 297, 300 (Minn. App. 1985), *citing Sullivan v, Credit River Township*, 299 Minn. 170, 176-77, 217 N.W.2d 502, 507 (Minn. 1974). *Accord Marshall County v. State of Minnesota,* 646 N.W.2d 570, 577 (Minn. App. 2001), relying upon *Idaho Farm Bureau Federation v. Babbitt,* 58 F.3d 1392, 1400 (9th Cir. 1995) (failure of an agency to take action within a time period set forth in a statute does not bar subsequent agency action unless there is a specific indication that such a bar was intended).

[49] *See, e.g., In the Matter of Proposed Amendments to Rules Governing the Minnesota Environmental Review Program*, 12-2901-15496-1 (2005) (EQB failed to adopt rules by Jan. 1, 2005, despite statement in authorizing legislation that it "shall" adopt rules relating to environmental review for recreational trails by that date. ALJ emphasized that the statute was directory and provided no penalty for failure to meet the Jan. 1, 2005, deadline, and found that the EQB's statutory authority to adopt the proposed rules had not expired).

[50] Exs. 7 and 8.

[51] SONAR at 75-76.

39. The Department maintains a distribution list regarding the proposed rule revision, which includes persons or entities self-identified or identified by the Department or others as interested in the revision. The Department has actively sought to add parties to the distribution list throughout the process. In November 2004, the Department implemented a free notification system through the GovDelivery.com subscription management service that automatically notifies interested parties whenever the Department's web page regarding these rules is updated. The email to interested parties includes a direct link to the updated web page.[52]

40. The Department has widely disseminated the proposed rules to affected parties and made substantial efforts to ensure that the interested public was involved in the entire process. Therefore, the Administrative Law Judge finds that the MDH has satisfied the notice requirements.

V. Impact on Farming Operations

41. Minn. Stat. § 14.111 imposes an additional requirement calling for notification to be provided to the Commissioner of Agriculture when rules are proposed that affect farming operations. In addition, where proposed rules affect farming operations, Minn. Stat. § 14.14, subd. 1b, requires that at least one public hearing be conducted in an agricultural area of the state.

42. The proposed rules do not affect farming operations. Although they set HRLs for groundwater, they do not regulate use of chemicals in farm operations. The Administrative Law Judge concludes that the Department did not, and was not required to, notify the Commissioner of Agriculture.

VI. Compliance with Other Statutory Requirements

A. Cost and Alternative Assessments

43. Minn. Stat. § 14.131 requires an agency adopting rules to include in its SONAR:

> (1) a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule;
>
> (2) the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues;
>
> (3) a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;
>
> (4) a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency

[52] SONAR at 76.

and the reasons why they were rejected in favor of the proposed rule;

(5) the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals;

(6) the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals; and

(7) an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.

44. With respect to the first factor, in its SONAR the Department asserts that the proposed rules could affect all persons living in Minnesota, because the HRLs are used as benchmarks that play a role in state groundwater monitoring and contamination response programs. Specifically, the proposed rules can affect individuals and populations when a private or public water supply becomes contaminated and federal Maximum Contaminant Levels (MCLs) are unavailable. The proposed revisions also provide a greater degree of protection to sensitive or highly-exposed populations, such as children, the very old, the sick, and the infirm.[53]

45. With respect to the second requirement, the Department states that this rulemaking will have no direct impact on state revenues because there are no fees or implementation and enforcement costs associated with the rules. According to the Department, state agencies applying the proposed HRLs will have to determine costs on a case-by-case basis.[54]

46. The third element requires the MDH to determine if there are less costly or less intrusive methods to achieve the purposes of the proposed rules. The fourth element requires the MDH to describe any alternate methods that it considered and why those methods were rejected. The MDH addressed these two requirements together, arguing that it has derived its HRLs using scientifically sound sources and methods that ensure the protection of all Minnesotans. If the agency in charge of an investigation regarding water quality determines that certain groups will not be exposed, that agency can exercise its discretion to apply a different value or manage known and potential risks in other ways.[55] The MDH has engaged in a lengthy process of exchanging ideas with interested individuals and groups, and that input is reflected in the changes to the rules and SONAR made between publication of the 2004 draft and publication of the current version of the proposed rules. According to the MDH, these rules represent the

[53] SONAR at 70, 71.
[54] SONAR at 70.
[55] SONAR at 71.

soundest calculations that MDH can supply to fulfill its mission without unduly restricting the parties who ultimately must observe them.[56]

47. With respect to the fifth factor, the Department must note the probable cost of complying with the proposed rules. According to the Department, the probable costs of complying with the proposed rules cannot be estimated because the HRL rules do not specify how the health-protective numbers are to be applied. HRLs are one of multiple sets of criteria used to evaluate whether the concentration of a contaminant found in groundwater is associated with a risk to health, and they are not intended to serve as "bright lines" between acceptable and unacceptable concentrations. The Department notes that because some of the revised HRLs are lower than the 1993/1994 values, the cost of remediating or preventing water contamination may increase. Conversely, because some of the revised HRLs are higher than the 1993/1994 values, some costs may decrease.[57]

48. With respect to the sixth factor, the MDH asserts that the cost or consequences of not adopting these rules is immeasurable. A reliable source of groundwater, safe for human consumption, is essential to the ability of a state to offer a high standard of living to its citizens. So the MDH argues that failure to revise the rules would ignore legislative directives and leave in place outdated standards that provide limited protections to segments of the population.[58]

49. With respect to the seventh factor, the Department explains that the EPA's Office of Water publishes several sets of standards and health advisories relating to drinking water, including Maximum Contaminant Level Goals (MCLGs), Maximum Contaminant Levels (MCLs), Drinking Water Equivalent Levels (DWELs) and Health Advisories (HAs). The Department's HRLs differ from the existing federal regulations in three ways. First, the Department's HRLs are strictly health-based. Second, the proposed HRLs provide guidance for both cancer and noncancer effects. Third, the Department's revised HRLs explicitly address risk to infants and children. According to the Department, while some federal regulations adhere to one or two of these conditions, none adhere to all conditions.[59]

50. As to the need and reasonableness of these differences between the proposed HRLs and the federal regulations, the Department argues that EPA-derived MCLGs are advisory values based solely on considerations of human health. Because the MCLG for any chemical that causes cancer is zero, and because it is highly difficult to restore contaminated groundwater to a pristine condition, the Department believes that MCLGs do not provide meaningful values for practical application to groundwater contaminated by carcinogens.[60]

---

[56] *Id.*
[57] SONAR at 71-72.
[58] *Id.*
[59] *Id.*
[60] *Id.*

51. EPA-derived MCLs are federal standards adopted for regulation of public drinking water in Minnesota. The Department argues in favor of its proposed HRLs because the MCLs incorporate a consideration of the costs required to reduce contaminant concentrations of a given level and the technological feasibility of reaching that level. According to the Department, such considerations may not be relevant to private drinking water wells or to other sites impacted by contamination.[61]

52. EPA-derived DWELs and HAs are estimates of acceptable drinking water levels of noncarcinogens based on health effects information, which serve as technical guidance to assist federal, state, and local officials. DWELs assume that all of an individual's exposure to a contaminant is from drinking water, while HRLs and HAs take into account an individual's exposure by means other than drinking water and allocate to drinking water only a portion of an individual's allowable exposure. As to HAs, the Department argues that it favors proposing revised HRLs over HAs because some HAs fail to incorporate a Relative Source Contribution (RSC) and others are calculated based only on adult intake and body weight.[62]

53. The Administrative Law Judge concludes that the MDH has fulfilled its obligation under Minn. Stat. § 14.131 to discuss costs and alternative assessments in the SONAR.

B. Performance-Based Regulation

54. Minn. Stat. § 14.131 also requires that an agency include in its SONAR a description of how it "considered and implemented the legislative policy supporting performance-based regulatory systems set forth in section 14.002." Section 14.002 states, in relevant part, that "whenever feasible, state agencies must develop rules and regulatory programs that emphasize superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals."

55. The Department explains that the proposed HRL rules allow stakeholders flexibility in determining how best to protect the public from potentially harmful substances. The proposed rules are based on science and policy, and stakeholders have options about which action to take and how to evaluate the results of those actions.[63]

56. The Administrative Law Judge finds that the MDH has met the requirements set forth in Minn. Stat. § 14.131 for assessing the impact of the proposed rules, including consideration and implementation of the legislative policy supporting performance-based regulatory systems.

---

[61] *Id.*
[62] SONAR at 73.
[63] *Id.*

C. Consultation with the Commissioner of Finance

57. Under Minn. Stat. § 14.131, the agency is also required to "consult with the commissioner of finance to help evaluate the fiscal impact and fiscal benefits of the proposed rule on units of local government."

58. The Department sent its proposed rules to the Commissioner of Finance on July 15, 2008.[64] On behalf of the Commissioner of Finance, Executive Budget Officer Craig Wieber replied on July 24, 2008. This response affirms the Department's assertion that the proposed rules add obligations for local units of government and that additional costs may be imposed on a case-by-case basis. But overall, the fiscal impact is likely to be minimal.[65]

59. The Administrative Law Judge finds that the Department has met the requirements set forth in Minn. Stat. § 14.131 for consulting with the Commissioner of Finance.

D. Cost to Small Businesses and Cities under Minn. Stat. § 14.127

60. Effective July 1, 2005, under Minn. Stat. § 14.127, agencies must "determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed $25,000 for: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees."[66] Although this determination is not required to be included in the SONAR, the statute states that the agency "must make [this] determination . . . before the close of the hearing record" and the Administrative Law Judge must review the determination and approve or disapprove it.[67]

61. The SONAR and the rulemaking record contain some evidence regarding costs associated with the proposed rules. In its discussion of the regulatory factors, above, the Department asserted that the probable costs of complying with the proposed rules could not be estimated because the rules do not specify how the health-protective numbers are to be applied.[68] The Department noted that the cost of remediating or preventing water contamination may increase for some entities and decrease for others. Furthermore, the Commissioner of Finance found that "additional costs may be imposed on a case by case basis, but the overall impact is likely to be minimal."[69] Based upon this evidence, it does not appear that the proposed rules would impose costs exceeding $25,000 in the first year on cities or small businesses. None of the interested parties providing comments in this rulemaking asserted that the anticipated cost of complying

---

[64] Ex. 11.
[65] *Id.*
[66] Minn. Stat. § 14.127, subd. 1.
[67] Minn. Stat. § 14.127, subd. 2.
[68] SONAR at 71-72.
[69] Ex. 11.

with the proposed rules in the first year after they become effective would exceed $25,000.

62. Unfortunately, however, the record in this rulemaking proceeding does not reflect that the Department made an explicit determination under Minn. Stat. § 14.127 concerning whether or not the costs of complying with the proposed rule in the first year after the rule takes effect would exceed $25,000 for small businesses or small cities. The Administrative Law Judge thus finds that the Department has not met the requirements set forth in Minn. Stat. § 14.127. This constitutes a defect in this rulemaking proceeding. To correct this defect, the Department must provide its determination under Minn. Stat. § 14.127 to the Chief Administrative Law Judge for review before it adopts the rules in final form.

VII. Rulemaking Legal Standards

63. Under Minnesota law,[70] one of the determinations that must be made in a rulemaking proceeding is whether the agency has established the need for and reasonableness of the proposed rules by an affirmative presentation of facts. In support of a rule, an agency may rely on legislative facts, namely general facts concerning questions of law, policy and discretion, or it may simply rely on interpretation of a statute, or stated policy preferences.[71] The Department prepared a Statement of Need and Reasonableness (SONAR) in support of its proposed rules. At the hearing, the Department relied upon the SONAR as its affirmative presentation of need and reasonableness for the proposed amendments. The SONAR was supplemented by comments made by Department staff at the public hearing, and by the Department's written post-hearing comments and reply.

64. The question of whether a rule has been shown to be reasonable focuses on whether it has been shown to have a rational basis, or whether it is arbitrary, based upon the rulemaking record. Minnesota case law has equated an unreasonable rule with an arbitrary rule.[72] Arbitrary or unreasonable agency action is action without consideration and in disregard of the facts and circumstances of the case.[73] A rule is generally found to be reasonable if it is rationally related to the end sought to be achieved by the governing statute.[74] The Minnesota Supreme Court has further defined an agency's burden in adopting rules by requiring it to "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken."[75]

---

[70] Minn. Stat. § 14.14, subd. 2; Minn. R. 1400.2100.

[71] *Mammenga v. Dept. of Human Services*, 442 N.W.2d 786 (Minn. 1989); *Manufactured Hous. Inst. v. Pettersen*, 347 N.W.2d 238, 244 (Minn. 1984).

[72] *In re Hanson*, 275 N.W.2d 790 (Minn. 1978); *Hurley v. Chaffee*, 231 Minn. 362, 43 N.W.2d 281, 284 (1950).

[73] *Greenhill v. Bailey*, 519 F.2d 5, 19 (8th Cir. 1975).

[74] *Mammenga*, 442 N.W.2d at 789-90; *Broen Mem'l Home v. Minnesota Dept. of Human Services*, 364 N.W.2d 436, 444 (Minn. Ct. App. 1985).

[75] *Manufactured Hous. Inst. v. Pettersen*, 347 N.W.2d at 244.

65. Reasonable minds might be divided about the wisdom of a certain course of action. An agency is legally entitled to make choices between possible approaches so long as its choice is rational. It is not the role of the Administrative Law Judge to determine which policy alternative presents the "best" approach, since this would invade the policy-making discretion of the agency. The question is, rather, whether the choice made by the agency is one that a rational person could have made.[76]

66. In addition to need and reasonableness, the Administrative Law Judge must also assess whether the Department complied with the rule adoption procedure, whether the rule grants undue discretion, whether the MDH has statutory authority to adopt the rule, whether the rule is unconstitutional or illegal, whether the rule constitutes an undue delegation of authority to another entity, or whether the proposed language is not a rule.[77]

67. Because the Department suggested changes to the proposed rules after original publication of the rule language in the State Register, it is also necessary for the Administrative Law Judge to determine if the new language is substantially different from that which was originally proposed. The standards to determine whether changes to proposed rules create a substantially different rule are found in Minn. Stat. § 14.05, subd. 2. The statute specifies that a modification does not make a proposed rule substantially different if:

> "the differences are within the scope of the matter announced . . . in the notice of hearing and are in character with the issues raised in that notice;"
>
> the differences "are a logical outgrowth of the contents of the . . . notice of hearing, and the comments submitted in response to the notice;" and
>
> the notice of hearing "provided fair warning that the outcome of that rulemaking proceeding could be the rule in question."

68. In reaching a determination regarding whether modifications result in a rule that is substantially different, the Administrative Law Judge is to consider:

> whether "persons who will be affected by the rule should have understood that the rulemaking proceeding . . . could affect their interests;"
>
> whether the "subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the . . . notice of hearing;" and
>
> whether "the effects of the rule differ from the effects of the proposed rule contained in the . . . notice of hearing."

---

[76] *Federal Sec. Adm'r v. Quaker Oats Co.*, 318 U.S. 218, 233 (1943).

[77] Minn. R. 1400.2100.

VIII. Analysis of the Proposed Rules

69. This Report is limited to discussion of the portions of the proposed rules that received critical comment or otherwise need to be examined, and it will not discuss each comment or rule part. Persons or groups who do not find their particular comments referenced in this Report should know that each and every suggestion, including those made prior to the hearing, has been carefully read and considered. Moreover, because sections of the proposed rules were not opposed and were adequately supported by the SONAR, a detailed discussion of each section of the proposed rules is unnecessary.

70. The Administrative Law Judge finds that the Department has demonstrated, by an affirmative presentation of facts, the need for and reasonableness of all rule provisions not specifically discussed in this Report. The Administrative Law Judge also finds that all provisions not specifically discussed are authorized by statute and there are no other problems that would prevent the adoption of those rule parts.

IX. Public Comments Concerning the Rule Revisions in General

A. Support for the Rule Revisions

71. Melanie Marty, Chief, Air Toxicology and Epidemiology Branch, California EPA Office of Environmental Health Hazard Assessment, a toxicologist by training, testified in support of the rule revisions. In particular, she commended MDH for taking into account the effect that chemicals may have specifically on infants and children, and attempting to address the effect of exposure to combinations of chemicals.

72. John Adgate, Associate Professor, Division of Environmental Health Sciences, University of Minnesota School of Public Health, has extensive background in exposure science, monitors toxicology and has worked as a risk assessor. Professor Adgate was the panel chair at the peer-review meeting convened by MDH to review the Department's proposed rule draft in November 2005. The panel's focus was on the proposed methodology, not on the specific HRL for any one chemical. Professor Adgate supported MDH's revisions because there is new information available since the standards were set in 1994, and, in particular, there is an increased focus on protecting infants and children and using peer-reviewed approaches. In his view, MDH was responsive to the comments made by the peer-review panel in 2005 and has made a good-faith effort to incorporate the panel's conclusions, stay abreast of risk assessment methodology, and rely on peer-reviewed science. He believes that MDH's proposed methodology for setting HRLs is reasonable and necessary.[78]

73. James H. Sherman, a toxicologist with Monsanto, had a few specific criticisms of the proposed rule revisions, including the HDLs for alachlor and acetochlor and MDH's decision to withdraw the HDL for alachlor ESA.[79] In general, Dr. Sherman

[78] Testimony (Test.) of Adgate at 29-31.

[79] Test. of Sherman at 33-44; additional discussion is reflected in comments of Acetochlor Registration Partnership, *infra*.

supported MDH's approach to setting the HRLs and believes that its approach will lead to good standards that are protective of human health.[80]

74. The Minnesota Department of Agriculture (MDA) expressed its support for the proposed rule revisions. MDA is the lead state agency for the registration of pesticide products and enforcement of legal pesticide use. The MDA defers to MDH for HRL calculations and related health risk assessment when groundwater contamination occurs. MDA would like to have HRLs derived for all pesticides and pesticide degradates, and acknowledges the level of resources and effort required to set them. It has appreciated the opportunity to participate in interagency meetings designed to prioritize HRL requests.[81]

75. The Minnesota Pollution Control Agency (MPCA) expressed its support for the proposed rules and for MDH's efforts to consider scientific research, EPA information and peer review in the rule development. MPCA looks forward to the development of additional HRLs that conform to the proposed methodology.[82]

B. Objections to the Rule Revisions

1. Difficulty of Public Participation

76. The Institute for Agriculture and Trade Policy (IATP), Clean Water Action (CWA) and Environmental Justice Advocates of Minnesota (EJA) objected to the onerous, lengthy process, extending over seven years, that led to the publication of the proposed rule revisions. Each group lamented the difficulty that members of the public have remaining involved with such technical material over an extended time period, and meaningfully participating in the process. Similarly, State Representative Karen Clark expressed concern that delay in updating HRLs does not serve the public interest, and she expressed the hope that future updates will proceed promptly.[83]

77. MDH acknowledges that the process has been prolonged and that the material is technical. It has, however, not only complied with the statutory provisions for public involvement in the rulemaking process, but it has taken additional steps to make information available to the public.

78. Without minimizing the concerns expressed, it is unavoidable that highly technical material will require a level of knowledge and study that is beyond the grasp of most members of the public. In part to address this, MDH sent out the rule revisions and SONAR for peer-review by persons with the expertise to evaluate and critique them. Although that is not a substitute for public involvement, it reflects the agency's willingness to subject its proposed revisions to careful, independent scrutiny. In rule proceedings such as this, the point of a public process is not to insure that every person

[80] Test. of Dr. James Sherman at 34.

[81] Greg Buzicky, Director, Pesticide and Fertilizer Management Division, MDA, Nov. 5, 2008.

[82] MPCA Comments, Oct. 10, 2008.

[83] Karen Clark, State Representative, Oct. 30, 2008 via fax.

can fully participate, but to assure that the agency's efforts are transparent and open to critique. MDH made changes to its draft rules in response to the peer review process, reflecting its commitment to consider public input. Moreover, the rulemaking hearing and public comment period provide additional opportunities to address concerns about the need for and reasonableness of the proposed rule revisions.

79. MDH's primary focus in this rulemaking has been to complete its revision of the methodology that will guide the development of additional HRLs and to meet the statutory directive to have some HRLs in place by the 2009 deadline. It intends to promptly begin development of additional HRLs when this rulemaking process is complete.[84]

2. Decrease in Number of Chemicals Addressed in the Rule Revisions

80. IATP, CWA and others objected to MDH's decision to decrease the number of specific chemicals addressed in the rule revisions from the 230 chemicals under discussion in 2002, at the start of the rule revision process, to the smaller number included in the current rule amendments. As CWA explains, the rules do not significantly increase groundwater protection, and the short list excludes arsenic and dioxin, two chemicals of concern. The small number is also troubling because new chemicals are introduced each year. The small number of chemicals that have been subjected to the rule process calls into question its adequacy in protecting public health.[85]

81. MDH explained in its comments that there have been many changes to the methodology to determine HRLs since 1993 and 1994 and that the new methodology is superior but requires a more labor-intensive, longer process for each chemical review. In response to peer review in 2005, MDH revamped the methodology. This required new evaluations of all chemicals included in the 2004 draft. In order to meet the legislative deadline of March 1, 2009, for the most commonly identified groundwater contaminants,[86] MDH focused its effort on revising the methodology and reviewing the highest priority chemicals. It intends to review additional chemicals and amend the rules as necessary and points out that Part 4717.7500 has not been repealed and will continue to provide guidance for an additional 105 chemicals.[87]

---

[84] Department's Post-Hearing Reply Comments, Nov. 6, 2008.

[85] Clean Water Action, Posthearing Comments, Oct. 30, 2008.

[86] Minn. Laws 2007, Ch. 147, Art. 17, Sect. 2.

[87] Department's Post-Hearing Comments, Oct. 30, 2008, at 2-3; Department's Posthearing Reply Comments at 1.

3. The 2008 Proposed HRL Values for Some Chemicals Are Higher Than the Draft 2004 HRL Values for Those Chemicals

82. Several commenters, including MCEA, IATP and EJA, objected that the 2008 proposed HRL values were higher than the levels in the 2004 draft HRLs and less protective of the public. Specifically, they contended that MDH had set four HRLs in the proposed rules that were lower than the 2004 draft values[88] and also adopted two MCLs that were lower than the 2004 draft values.[89]

83. MDH does not agree that a higher HRL implies that the 2008 proposed value is any less protective of health.[90] MDH asserts that the more appropriate point of comparison is the 1993/94 HRLs rather than the 2004 draft HRLs. The 2004 draft HRLs were distributed to solicit comment, and, in response, changes were made to the underlying methodology. These changes limited the number of HRL reviews that could be completed. However, under the 2008 proposed rules, the intake rates are typically higher and the proposed HRLs are typically lower than the 1993/94 HRL when toxicity remained the same. The 2008 proposed values in some cases reflect more recent toxicity reviews or adoption of the EPA MCL. Overall, MDH asserts that the 2008 proposed levels are an improvement over the 1993/94 values because the new methods "address intake rates across all lifestages, use current toxicity and intake data, and incorporate the best and most recent science available."[91]

84. It is not unreasonable for MDH to propose a rule revision that differs from an earlier draft addressing the same topic. MDH has demonstrated that it sent out its 2004 draft for peer review, made changes to the methodology to comport with the responses it received, and was compelled to set some limits by the 2009 statutory deadline. For some chemicals, MDH set a new HRL based on its revised methodology. For the others, MDH was not able to conduct an independent review of all of the chemicals and therefore resorted to the alternative in the statute, to use the MCL for the chemicals.

4. Confusion About Which HRLs Apply

85. The Minnesota Pollution Control Agency would like to assure that there is no confusion about which HRLs are in effect. In addition to the HRLs included in this rule, MDH has not repealed Minn. R. 4717.7500, which lists the HRL for many additional chemicals.

86. Following publication of the proposed rule, MDH recognized that it would be helpful to add a provision addressing the transition to the new HRLs and proposed adding Minn. R. 4717.7860, subpart 25, discussed in greater detail, *infra.* It clarifies that

---

[88] Acetochlor, alachlor, cis 1,2-dichloroethylene and vinyl chloride.

[89] Pentachlorophenol, and 2(2,4,5-trichlorophenoxy)propionic acid.

[90] *See e.g.* Environmental Justice Advocates of Minnesota, Oct. 17, 2008; Clean Water Action, Posthearing Comments, Oct. 30, 2008.

[91] Department's Post-Hearing Comments, Oct. 30, 2008, at 3.

the HRLs set in Minn. R. 4717.7500 will remain in effect until specifically replaced by new HRLs set under the proposed methodology. MDH will also update its web pages, which MDH believes are the primary source of information for risk managers, to include information about which HRLs have been revised.

5. Methodology for Determining Health Based Values (HBVs)

87. 3M expressed concern that MDH has not committed to following the methodology in the proposed rules for setting Health Based Values (HBVs), and that, because of the small number of HRLs, there will be reliance on the HBVs. It requests that MDH be directed to follow its proposed rules in setting HBVs to assure that they rely upon an established methodology.[92] CropLife America also expressed a preference for assuring that the methodology for setting HBVs is clear, and it also asks that the steps for incorporating new toxicology data be clarified.[93]

88. The Department responded that the HBVs are beyond the scope of this rulemaking. It restated its commitment to move ahead with development of HRLs and minimize the time that HBVs remain in effect as interim measures.

6. Selection of the "Commonly Detected Contaminants"

89. Some commenters objected to the process by which MDH selected the ten most commonly detected contaminants, as required by the 2007 legislation.[94] MDH conferred with the Minnesota Department of Agriculture and Minnesota Pollution Control Agency to develop its ranking, and ultimately it selected thirteen contaminants to include in this rulemaking proceeding. CropLife America contended that the selection was intended to be empirical rather than qualitative.

90. The Department's process for selecting the most commonly detected contaminants is explained in the SONAR, pages 12-14. In the Department's Posthearing Reply Comments at page 5, it points out that no comprehensive contaminant assessment has been conducted for all groundwater in Minnesota. By relying on the experience of the state agencies that routinely review and evaluate information about groundwater contaminants, including quantitative information, and by selecting thirteen chemicals rather than ten, MDH is confident that it has addressed the intent of the statutes.

91. Since neither specific chemicals nor a specific method for selecting the commonly detected contaminants were set forth in the statute, and MDH engaged in a thoughtful process to determine them, the Administrative Law Judge concludes that the method used by MDH to select the most commonly detected contaminants was reasonable and complies with the language of the statute.

---

[92] 3M Posthearing Comments, Oct. 30, 2008, at 17.

[93] CropLife America, Posthearing Comments, Oct. 30, 2008.

[94] Minn. Laws 2007, Ch. 147, Art. 17, Sec. 2, requiring the commissioner of health to adopt rules relating to HRLs for the ten most commonly detected contaminants by March 1, 2009.

X. Rule-by-Rule Analysis

Part 4717.7810 Health Risk Limits: Purpose and Scope

92. The purpose of the proposed rules is to establish the HRLs for substances found in Minnesota groundwater, as derived by MDH or by application of the federal MCLs. In these rule revisions, MDH has included HRLs derived from its own studies and adopted the MCLs for other chemicals. The rule revisions are also consistent with Minn. Stat. §§ 103H.201, to set HRLs for substances degrading the groundwater.

A. Use of HRLs in Risk Management

93. As stated in Subpart 2 B of the proposed rule, HRLs are for use by public agencies and private entities in Minnesota to determine whether groundwater has been impacted by human activity and should be subject to regulatory or advisory actions based on human health concerns. The HRLs are intended to be health-protective upper limits for contaminants found in groundwater that may be used as drinking water and to take into account potential human health effects from ingestion. HRLs are not intended to directly address human exposure through other means, such as skin contact or inhalation, or through contact with other non groundwater media, such as food or soil. The HRLs do not address the protection of aquatic life, animal life, or links between ecological and human health. Thus, HRLs are not intended as levels generally appropriate for protection of the environment.

94. MDH does not apply or enforce application of the HRLs. Other agencies may adopt HRLs for regulatory purposes. Depending on the circumstances of a particular site, a risk manager may consider modifying the HRLs, and may take into account economics and technological feasibility in order to establish realistic goals for remediation or protection of groundwater, as well as the characteristics of the population likely to be exposed, the source of the pollution, the chemical, and information about the nature and duration of exposure.[95]

95. 3M recommends that MDH develop a process for site-specific adaptation of HRLs.[96] MDH points out that site-specific adaptation of HRLs is beyond its authority. Implementing agencies use the HRLs as one tool to assess potential human health risk from contaminated groundwater, and the characteristics of the specific site will affect that risk assessment. Since conditions will vary, MDH will continue to work with other agencies to assess the application of the values and methodology to a specific site.[97]

---

[95] SONAR at 69-70. *See also* SONAR at 7 (use of the Exposure Decision Tree in determining RSC); at 15, 86, 117, 166 (use of the HRL may depend on site-specific characteristics; a risk manager may choose to apply a site-specific RSC).

[96] 3M Posthearing Comments, Oct. 30, 2008, at 14. *See also* Minnesota Chamber of Commerce Comments, originally submitted to MDH Dec. 20, 2007.

[97] Department's Posthearing Comments, Oct. 30, 2008, at 7.

B. Chemical Management Policy

96. IATP, CWA and EJA expressed concern that the rules address the safe levels of chemicals in groundwater rather than enhancing "chemical management" efforts to prevent the chemicals from getting into the groundwater. Although MDH acknowledged the concern, it cited its limited authority to set HRLs rather than general authority to restrict the use or release of chemicals.[98] The proposed rule specifically states: "HRLs specify a minimum level of quality for water used for human consumption, such as ingestion of water, and do not imply that allowing degradation of water supplies to HRL levels is acceptable."[99]

97. The ALJ concludes that the rule as proposed is necessary and reasonable.

4717.7820 Definitions

Subpart 3: ADAFs or Age-Dependent Adjustment Factors

98. The "age-dependent adjustment factors" are default modifiers to the cancer slope factor "that account for the increased susceptibility to cancer from early life exposures to linear carcinogens in the absence of chemical-specific data," and they are set at three levels: an adjustment of "10" from birth until two years of age; an adjustment of "3" from age two up to 16 years of age, and "1," effectively no adjustment, from 16 years of age and older.

99. The cancer slope factor is defined in subpart 23 of this proposed rule, and is the upper-bound estimate of risk per increment of dose that can be used to estimate cancer risk probabilities for different exposure levels. It is expressed as cancer incidence per mg/kg-day. Minn. Stat. § 103H.201, subd. 1 (d), requires MDH to use cancer slope factors published by the EPA to derive cancer HRLs. The ADAFs are adjustments to the cancer slope factors to account for increased susceptibility to cancer from early life exposures in the absence of chemical-specific data and are components of the methodology for setting the HRL for cancer, Part 4717.7840 (proposed).

100. In its SONAR, MDH explains that as the field of risk assessment has advanced since the HRLs were issued in 1993/94, scientists and policymakers have questioned whether models derived from studies of adults are protective of children. Exposure to certain chemicals at certain developmental periods may result in life-long consequences.[100] In 2001, the Minnesota Legislature enacted a provision requiring MDH to incorporate a reasonable margin of safety to protect infants and children and take into account specified health outcomes.[101]

---

[98] Department Post-Hearing Comments at 1.
[99] Minn. R. 4717.7810, subp. 2 B (proposed).
[100] *See, e.g.,* SONAR at 18.
[101] Minn. Stat. § 144.0751.

101. The proposed ADAFs were derived from the EPA Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens and are intended to account for increased cancer potency in the cancer slope factor when exposure occurs early in life.[102]

102. The American Chemistry Council (ACC) asserts that it is inappropriate to include age-dependent adjustment factors to the cancer slope in the methodology for determining the cancer HRL. It contends that children are not always more susceptible or sensitive to chemical substances in their environments, and that any categorical assertion to the contrary cannot be substantiated and misapplies EPA information. ACC cited studies to support its assertion. Because of this objection to MDH's proposed methodology, the Council asserts that MDH should suspend adoption of any new HRLs. In its view, chemical susceptibility of children should be considered for each specific chemical and general adjustments are inappropriate. In this respect, the Council challenges both the cancer potency age-dependent adjustment factor and the intake adjustment, discussed below.[103]

103. Although EPA has recommended the age adjustments only for carcinogens that have a "mutagenic" mode of action (*i.e.* that alter the DNA), MDH has adopted this approach for all linear carcinogens, regardless of the mode of action. Dr. Melanie Marty testified that the California EPA has taken the same approach in its air toxics programs and expects to use them in other areas in the future, in the absence of chemical-specific data. She offered examples of chemicals that act hormonally (and not through gene mutation) such as diethylstilbestrol, that show early age sensitivity.[104] MDH will use chemical-specific information regarding life-stage sensitivity in place of the default approach if available and reliable.

104. The ACC objected to MDH's use of default adjustment factors to account for potential sensitivities due to early-life exposure for those substances that act by non-mutagenic modes of action.[105] The Council pointed out that the EPA had fully considered the recommendation of some members of its Review Panel to apply default adjustment factors for carcinogens acting through a non-mutagenic mode of action and had declined to adopt that approach, based on its analysis and policy positions. Instead, the EPA uses a linear low-dose extrapolation approach without adjustment in the absence of chemical-specific data indicating differential early-life sensitivity. The ACC agrees with the EPA approach and asserts that the MDH approach is unreasonable. It recommends that the definition of "age-dependent adjustment factors", 4717.7820, subp. 3 (proposed), be amended to limit the use of the default modifiers to carcinogens that operate through a mutagenic mode of action. It advocates use of the linear low-dose extrapolation approach, without age-dependent adjustment factors in other instances.

---

[102] SONAR at 4, 23-24.

[103] American Chemistry Council, Posthearing Comments, Nov. 8, 2008.

[104] Test. of Marty 25-27.

[105] American Chemistry Council, Nov. 6, 2008; *See also* Ex. 14 and Minnesota Chamber of Commerce Prehearing Comments, Dec. 20, 2007.

105. CropLife America (CLA)[106] raises similar objections to the age-dependent adjustment factors. It contends that such adjustments should be applied only on a chemical-specific basis and only to carcinogens acting through a mutagenic mode of action, citing EPA policy.

106. IATP, CWA and EJA expressed support for taking into account the possible increased risk to infants and children in the HCL algorithms, including the age-dependent adjustment factor. Dr. Melanie Marty, California EPA, also supported consideration of the intake rates for infants and children and the age when exposure to the chemical takes place, in particular when there is evidence that children may be affected by the chemical during the development process.[107]

107. MDH disagrees with the ACC and others who opposed the age-dependent adjustment factors. It contends that many new documents, including EPA reports and journal articles, have addressed the increased sensitivity and exposure during early life stages, and it points to the Minnesota Legislature's directive to give special attention to the effect of exposure at various life stages.[108] The SONAR describes the types of studies that have been performed and the possible gap in information about early-life exposure.[109] Dr. Marty supported MDH's view that age-dependent adjustment factors are appropriate,[110] and the MDH Expert Advisory Panel members agreed, with one dissent, that the adjustment factors were warranted.[111] No objections were received to the specific values selected for the age adjustments.

108. MDH has also explained its decision to apply the adjustment factors to carcinogens with both a mutagenic and non-mutagenic mode of action. These are fully explained in the SONAR[112] and in its Posthearing Comments, submitted on October 30, 2008, at page 9. Although the MDH approach differs from the approach taken by the EPA for chemicals that operate by a non-mutagenic mode of action, MDH has provided a reasoned explanation for its decision to apply the age adjustment factors to chemicals operating by both a mutagenic and non-mutagenic mode of action.

109. MDH also points out that the proposed rules include HRLs for two linear carcinogens, dieldrin and vinyl chloride, where the cancer slope factors were adjusted, not by the default values, but by using data derived from studies of early-life exposure. MDH contends that this demonstrates that there is a biological basis for its approach,

---

[106] CropLife America (CLA) represents more than 80 developers, manufacturers, formulators and distributors of pesticides used by U.S. farmers and growers. Posthearing Comments, Oct. 30, 2008.
[107] Transcript at 22-27. Dr. Marty testified at the rule hearing via videoconference.
[108] Department's Posthearing Comments at 7-9, Oct. 30, 2008.
[109] SONAR at 52-63.
[110] Test. of Marty at 23-27.
[111] SONAR at 56.
[112] SONAR at 52-59.

and also demonstrates that MDH will use data rather than default adjustments when the data is available, as stated in Part 4717.7840, subp. 3 (proposed).[113]

110. The ALJ concludes that MDH has demonstrated the need for and reasonableness of the proposed definition and use of age-dependent adjustment factors to derive HRLs for cancer.

Subpart 4: Additional Lifetime Cancer Risk

111. This term is defined as "the probability that daily exposure to a carcinogen over a lifetime may induce cancer." The Department of Health uses an additional cancer risk of $1x10^{-5}$ (1 in 100,000) in its formula set forth at Part 4717.7840 (proposed) to derive cancer HRLs.

112. As stated in the SONAR, "Most carcinogens are typically subject to the conservative assumption that no exposure is without risk."[114] The HRL is based on the potency of the chemical and the anticipated intake rate of that chemical over a lifetime. MDH has historically relied on 1 in 100,000 as the appropriate level of increased risk for deriving HRLs. MDH explains in the SONAR:

> An additional cancer risk of 1 in 100,000 means that if a population of 100,000 were exposed to a specific concentration of a carcinogen, at most, one case of cancer would be expected to result from this exposure. Because the calculations use a 95 percent confidence interval, the true risk is likely to be lower. To put this 1 in 100,000 risk in perspective, currently one of every two Minnesotans will have some type of cancer by the end of their lifetime (a cancer risk of 50,000 per 100,000). This is considered the background cancer risk in Minnesota and in the United States over all. Their risk from exposure to a HRL chemical is considered an additional cancer risk.[115]

113. Several commenters objected to MDH's continued use of 1 in 100,000 increased cancer risk, preferring that the more stringent standard of 1 in 1,000,000 be used because it is more consistent with the EPA's goal of having zero excess population risk from environmental carcinogens and EPA's recommendation to states to regulate at the more protective level of 1 in 1,000,000. The MCEA pointed out that several states apply the more protective cancer risk level to drinking water.[116] The

[113] Department's Posthearing Comments at 9, Oct. 30, 2008.
[114] SONAR at 34.
[115] SONAR at 52.
[116] *See* MCEA Prehearing Comments, Sept. 27, 2008, Attachs. V (Massachusetts), W (Vermont) and X (Illinois); Test. of Yamin at 54 (New Jersey, California).

commenters are concerned about the high cancer rate for humans and increasing evidence that environmental toxicants may be contributing to the high rates.[117]

114. MDH acknowledges that there has been a debate about the appropriate risk level, and it has attempted to weigh the various positions in making its policy selection. It believes that the selected cancer risk level is reasonable and protective of public health and that other aspects of the HRL methodology (of which the additional lifetime risk is one small part) are conservative. It also points out that the selected risk level assumes an incremental change in cancer incidence among those who are exposed at a level equal to the HRL. Thus, the actual increased incidence in the population is much less.[118]

115. The EPA recommended range is 1 in 10,000 to 1 in 1,000,000. Although a tougher risk level could be justified, the ALJ concludes that MDH has demonstrated that its selected value of "additional lifetime cancer risk" as 1 in 100,000 is necessary and reasonable.

Subpart 14: Intake Rate or IR

116. In deriving HRLs for both noncancer and cancer, MDH assumes that groundwater will serve as the primary source of drinking water. Thus it includes an estimate of water intake in the equation for determining the HRL in Part 4717.7830 (proposed), for toxic effects other than cancer, and Part 4717.7840 (proposed), for cancer. Studies of water consumption show that adults ingest a greater volume of water than infants and children, but that, per body weight, ingestion by infants and young children is generally greater. In determining the algorithm for noncancer risk, MDH looked at the intake rate for a given duration and the proportion of exposure to the chemical that comes through drinking water, the "Relative Source Contribution (RSC)".[119] A similar adjustment is made for cancer risk.[120]

117. Generally, HRLs provide protection against adverse health effects from long-term exposure to contaminants in drinking water. However, the HRLs must also protect against adverse effects from shorter exposures, and take into account variations in the magnitude and duration of exposure, as well as sensitive life stages and subpopulations.

A. Toxic Effects Other Than Cancer

118. To evaluate intake, the EPA has recommended the evaluation of multiple exposure durations for the derivation of noncancer risk: acute – repeated dosing for a period of 24 hours or less; short-term – repeated dosing for more than 24 hours, up to

---

[117] *See, e.g.,* Ex. 15, Comments of Kathleen Schuler, Institute for Agriculture and Trade Policy; T. 57 (Schuler); MCEA Prehearing Comments, Sept. 17, 2008; Environmental Justice Advocates of Minnesota, Oct. 17, 2008.

[118] Department's Post-Hearing Comments at 5, citing the SONAR at 52 *ff*.

[119] SONAR at 41-42; *See* Part 4717.7830 (proposed).

[120] *See* Part 4717.7840 (proposed).

30 days; subchronic – repeated dosing for more than 30 days, up to approximately ten percent of a lifespan in humans[121]; and chronic - repeated dosing for more than approximately ten percent of a lifespan in humans.[122] The MDH external Expert Advisory Panel supported MDH's choice to evaluate less-than-chronic exposure durations to ensure that shorter periods of exposure were adequately protected.[123]

119. MDH has used EPA data to calculate default water intake rates for the various durations in its derivation of noncancer HRLs. MDH selected the following default duration-specific intake rates: acute or short-term – 0.289 liters per kilogram per day (L/kg-day), based on the 95th percentile intake from 1 month up to 3 months of age; subchronic – 0.077 L/kg-day, based on a time-weighted average (TWA) of the 95th percentile intake from birth up to 8 years of age; and chronic – 0.043 L/kg-day, based on TWA of the 95th percentile intake over a lifetime of approximately 70 years of age.[124]

120. CropLife America objects to the derivation of HRLs for different exposure periods, unless there are data for the corresponding duration. It contends that adjustment is not appropriate. MDH responds that for each HRL duration, there is a duration-specific toxicity value (RfD) paired with a time-weighted average intake rate. Thus, the use of the differing exposure rates is justified, and is not arbitrary.[125]

121. In order to assure that it was selecting a level of intake that would ensure an adequate margin of safety for most of the population, MDA chose the level of intake that would apply to the 95% percentile in determining intake for both the noncancer and cancer methodologies. It is consistent with the EPA's "high-end" exposure level, defined as the part of the exposure distribution that is between the 90th percentile and the 99.9th percentile. The EPA survey did not fully account for subpopulations that used only one source of water for ingestion. Such individuals may consume more tap water than the national estimates provide. The potential for underestimating ingestion is more pronounced for infants. Thus, MDH selected intake rates that include most of the population and will be protective of individuals who consume a large percentage of their water from a single source.[126]

122. The Chamber of Commerce contends that MDH has provided insufficient support for selection of the 95th percentile of intake and that the level selected by MDH

[121] MDH used a life expectancy of 78 years. SONAR at 5.

[122] Part 4717.7820, subp. 9 A.

[123] SONAR at 44-45.

[124] SONAR at 43-47. Although age 70 is lower than the life expectancy of the U.S. population, it corresponds with the duration over which health effects are typically assessed in chronic studies, and has remained the standard definition of "lifetime." SONAR at 6.

[125] Department's Posthearing Reply Comments, Nov. 6, 2008, at 5. *See also* SONAR at 44*ff*.

[126] SONAR at 45.

is greater than the 90th percentile rate typically used by the EPA.[127] This concern is shared by 3M.

123. Dr. Melanie Marty, California EPA, supported MDH's decision to consider the appropriate intake rates for infants and children because of the complex developmental processes occurring as they grow. In particular, she supported using the 95th percentile intake rates for infants and young children, a level that she believes will provide adequate protection for infants and children, and weighting exposure based on the age it occurs.[128]

124. MDH defends its choice of the 95th percentile intake rates because the HRL for both cancer and noncancer effects should be protective of persons who consume a lot of water from a single source and because it is based in part on the EPA Science Advisory Board's recommendations.[129] Although a different level might be acceptable, MDH had the discretion to select a value that will assure that the consumption levels of most Minnesotans will be covered. It is necessary and reasonable to include the 95th percentile intake rate in the definition.

125. MDH also considered life-stage sensitivity in establishing the appropriate intake rate. When the developmental period was *in utero*, the reference dose for the effect would be based on maternal exposure, (*i.e.,*0.043 L/kg-day, based on the 95th percentile intake rate). When the developmental effects were not limited to *in utero* exposure, MDH selected the acute and short-term default intake rate for infants aged 1 month up to 3 months (*i.e.*, 0.289 L/kg-day, based on the 95th percentile rate) as the default intake for deriving HRLs.[130] This approach was supported by the MDH Expert Advisory Panel.[131] Where sufficient chemical-specific information indicates that a different duration or intake rate is more appropriate, MDH will use that data.[132]

126. The conditions for using the proposed default approach for life-stage sensitivity were not met for any of the specific chemicals included in this rule revision. That is, there was sufficient chemical-specific information so that this general approach was not taken, but MDH has included default values for life-stage sensitivity for possible use in future chemical assessments.[133]

127. The Chamber of Commerce and CropLife America objected to using a more conservative intake rate for any derivation of an HRL that is based on a developmental endpoint, claiming that this adds an additional layer of conservatism that

---

[127] *See* Letter from Mike Robertson, Environment & Natural Resources Committee, Minnesota Chamber of Commerce, Dec. 20, 2007, resubmitted as public comment in this proceeding (email to Larry Gust from Mike Robertson, Oct. 17, 2008).
[128] Test. of Marty at 23.
[129] Department's Post-Hearing Comments, Oct. 30, 2008, at 7.
[130] SONAR at 6, 46.
[131] SONAR at 46.
[132] SONAR at 6.
[133] SONAR at 46.

is not scientifically based. As an example, the Chamber of Commerce states: "if the endpoint of toxicity is a post-natal effect, in the case of a chronic or subchronic HRL derivation, use of the developmental-specific intake values could change the calculation by a factor of 5-fold (subchronic) or 10-fold (chronic)."[134] It asserts that MDH has failed to scientifically justify such conservative intake rates.

128. MDH has fully explained its policy choices, and the Legislature's specific directive to consider age and developmental effects in its calculation of intake rate.[135]

B. For Cancer

129. In the derivation of cancer risk, the following durations, associated with the ADAFs, were selected: two-year duration for the birth to two-year age group; 14-year duration for the two- to 16-year age group; and 54-year duration for the 16 and older age group.[136]

130. The American Chemistry Council objected to MDH's proposed adjustment factor and asserted that such an adjustment is inconsistent with the approach taken by the EPA in evaluating childhood exposure to environmental contaminants.[137] The EPA uses an approach that sums the intake of a chemical during each discrete exposure period to more accurately estimate dose over a lifetime. Published EPA guidance sets age-specific intake rates for various media. The Council asserted that this standard approach is scientifically justified, while the MDH approach is not, and that the EPA approach is sufficiently conservative to protect children.[138]

131. As with the adjustments for the noncancer effects, MDH has fully explained its deviation from the EPA standards and its reasons for them.

132. ALJ concludes that MDH has demonstrated the need for and reasonableness of the definition for Intake Rate.

Subpart 21: Reference Dose or RfD

133. MDH has defined "reference dose" or "RfD" as an estimate of a dose for a given duration to the human population, including susceptible subgroups, that is likely to have no appreciable adverse effect during a lifetime. The reference dose is a component of the noncancer HRL algorithm. In the SONAR, MDH states that the definition is based on the one provided by the EPA but the definition and its use in the HRL process differ "in several substantive ways," which it details, including variation to

---

[134] Minnesota Chamber of Commerce Comments, originally submitted to MDH Dec. 20, 2007.

[135] *See, e.g.,* Minn. Stat. § 144.0751 (a).

[136] Part 4717.7820, subp. 9 B (proposed) (using the EPA's 70-year life expectancy, as explained in the definition of ADAFs).

[137] American Chemistry Council, Ex. 14, Attach. A to comments to MDH submitted Nov. 8, 2004.

[138] Ex. 14.

the exposure duration, the period over which adverse effects may develop, and elimination of the limitation to the oral route of exposure.[139]

134. The Acetochlor Registration Partnership (ARP) strenuously objects to this definition. It emphasizes the significance of the reference dose in the noncancer HRL algorithm as the only effectively variable input in the equation. It asserts that the term "reference dose" has a very precise meaning used by the EPA to derive toxicity value, and to redefine the same term and incorporate it into the algorithm for noncancer HRLs is unreasonable. It also asserts that, by doing so, MDH has failed to conform to its stated intent, to incorporate the best and most recent science available. Instead, for each of the three chemicals addressed by ARP (acetochlor, alachlor and alachlor ESA), none of the HRLs were calculated using the EPA's determination of RfD.[140]

135. MDH has fully explained its bases for defining RfD differently from the EPA and why its definition is consistent with its legislative mandate to protect sensitive subgroups. Its intent is to define a reference dose that is sufficiently protective for a given duration by identifying the lowest dose with an adverse effect or the precursor to an adverse effect. MDH will not set HRLs for chemicals with no adverse effects.[141]

136. The selection of an RfD requires determination of the dose threshold below which the body eliminates the chemical with no ill effect, or alternatively, it is based on mathematical models associated with a predefined effect level that calculates a "benchmark dose." Part 4717.7860 (proposed) sets forth the RfD for each chemical, and the health effect upon which it was based. Since not all animal studies are conducted on humans, the level of dosing that affected the species that was studied must be converted to a "Human Equivalent Dose" (HED). MDH has followed EPA's two preferred models to calculate chemical-specific HED's when studies on human dosing are not available.[142]

A. Duration Specific Reference Doses

137. An EPA panel reviewing reference dosing recommends that the RfD be protective of adverse effects for a given duration. In response to this recommendation and the statutory directive to derive HRLs that are protective of infants and children and account for developmental effects. In some instances duration-specific reference doses for shorter durations were more protective than for longer durations. In those cases, the more limiting RfD was selected for longer durations.[143]

138. The ACC objects to MDH's decision to adjust a chronic HRL value where a short-term HRL has been calculated and is lower than the chronic HRL value. In its view, the chronic HRL is based on scientific data, and it is a general principle of

[139] SONAR at 84-85.
[140] Acetochlor Registration Partnership, Posthearing Reply Comments, Nov. 6, 2008.
[141] SONAR at 27-28, 85.
[142] SONAR at 28-30.
[143] SONAR at 33-34.

toxicology and dose-response that toxicity potential increases as exposure duration increases. The ACC claims that it is inappropriate and arbitrary to replace the results of a chronic study with a health criterion from a short term study.

139. MDH accepts the general proposition that shorter-duration RfDs would typically be higher in absolute value than the longer-duration RfDs. However, the target organ for shorter durations may differ or the endpoint assessed in a shorter-term study could be more sensitive or assessed in a different species or at a different life stage. MDH states: [i]n the event that the shorter-duration RfD is more limiting (*i.e.,* lower) than the calculated longer-duration RfD, the longer-duration RfD will be set so as not to exceed the more limiting, shorter-duration RfD value." MDH asserts that this approach is consistent with EPA recommendations and with recent EPA practice.[144]

B. Uncertainty Factor

140. Uncertainty and variability factors account for what is not known about a chemical's toxicity to a human population. Once the dose level is selected, it is divided by uncertainty and/or variability factors to derive the reference dose. There are five factors, each is typically assigned a value, typically 1 to 10, and then multiplied to determine the overall uncertainty factor. Two factors, the interspecies factor and the intraspecies factors are nearly always applied, reducing doses derived from animal studies by 100-fold or more. MDH has applied the uncertainty factors to the calculation of the RfD in a manner consistent with the EPA guidance, as fully set forth in the SONAR.[145] If the uncertainty factors associated with the chemical's toxicity exceeded 3,000, MDH deemed that it had insufficient chemical information to derive an RfD (and therefore an HRL). MDH states that "in keeping with this recommendation and the rationale supporting it, MDH has not derived a HRL for any chemical if the product of all applicable uncertainty factors exceeds 3,000."[146]

141. The Acetachlor Registration Partnership, 3M and Minnesota Chamber of Commerce request that the rules include more information about the uncertainty factor in the HRL methodology, and a specific statement that an uncertainty factor exceeding 3,000 will not be used to calculate the appropriate RfD. The EPA Technical Panel also recommended against setting a reference value when the uncertainty calculation exceeded 3,000.[147]

142. MDH has responded that the proposed rules do not set forth the individual parameters (*e.g.,* point of departure, total uncertainty factor) used in the derivation of the RfD, but it has listed in Part 4717.7860 (proposed) each chemical's RfD for each duration for which it has derived an HRL. The process for determining the RfD has been set forth in the SONAR.

---

[144] SONAR at 34, 50-51. *See also* Department's Posthearing Comments, Oct. 30, 2008, at 10.
[145] SONAR at 31-32.
[146] SONAR at 3, 31-32.
[147] Department's Posthearing Reply Comments, Nov. 6, 2008, at 10.

143. Each proposed RfD is set forth in the rule and is subject to comment in the rulemaking process. Since the proposed RfD for each chemical is set forth, members of the public had the opportunity to review them and determine if there were errors in the calculation. Thus, the ALJ concludes that the initial dose and uncertainty factors used in each calculation do not need to be included in the rule.

144. Although MDH has not used an uncertainty factor greater than 3,000 to set an RfD in these rule revisions, it is not willing to limit its determination of the RfD to data with resulting uncertainty factor of 3,000 or less. It states: "circumstances may arise that make it necessary (*e.g.,* quick response to a new contaminant, widespread use and potential exposure to a contaminant) to derive guidance despite limited toxicity data. Therefore, MDH is not limiting future use of a cumulative uncertainty factor greater than 3,000 for the development of risk assessment advice."[148]

145. MDH's explanation for failing to state the uncertainty limitation in the rule is not reasonable. It has acknowledged that a higher level of uncertainty signals that the data cannot be relied upon. Thus, even in unusual circumstances, setting a limit that lacks substantial scientific validity is unreasonable and inconsistent with its expressed intent in the SONAR. MDH has failed to cite any authority for its statement that a meaningful RfD and HRL can be set when the uncertainty factor exceeds 3,000, nor has it set forth the criteria that would apply for exceeding that limit.

146. A limitation to the calculation that is directly tied to the reliability of the calculation and can significantly reduce the RFD is a general principle that meets the definition of "rule," an agency statement of general applicability and future effect,"[149] and should be included as a proposed rule, along with the criteria for deviating from the general statement, if warranted. This defect can be corrected in two ways – by stating in 4717.7830 subp. 1 (proposed) that no HRL will be derived when the uncertainty factors exceed 3,000 or by including the limitation in the definition of Reference Dose, 4717.7820, subp. 21 (proposed), and adding the criteria, if any, for deviation. Since the limitation is fully discussed in the SONAR and spelling it out more clearly would not change any HRL, modification of either rule to include the limitation on the uncertainty factors would not constitute a substantial change from the rules as published in the State Register.

147. MDH has fully explained its basis for altering the EPA's definition of reference dose and substituting its own definition. It has also fully explained how the reference dose will be calculated.

148. ALJ concludes that the definition of reference dose is reasonable and necessary as proposed, with the exception that it must be amended to incorporate the limitation on the uncertainty factor, as more fully set forth above.

---

[148] Department's Posthearing Reply Comments, Nov. 6, 2008 at 10.

[149] Minn. Stat. § 14.02, subd. 4.

Subpart 22: Relative Source Contribution or RSC

149. The Relative Source Contribution (RSC) is the fraction of total exposure to a chemical that is allocated to drinking water. The RSC is a component of the equation that sets the RfD for noncancer effects, taking into account that some exposure to the chemical may come from other sources, such as inhalation and absorption through the skin. This definition includes default RSCs: 0.5 for acute and short-term HRLs, and 0.2 for subchronic or chronic HRLs. MDH explains its basis for the selection of these values in the SONAR. Because there is little site-specific data available, MDH has relied on a "decision tree process" produced by EPA. It includes a series of decision points that lead to an appropriate RSC. EPA recommends a floor value of 20 percent (0.2) and a ceiling of 80 percent (0.8) for the RSC. The 20 percent floor reflects the assumption that the major portion of the total exposure comes from other sources, such as diet. Because the decision tree model is intended for use in site-specific application, MDH has selected the conservative floor of 0.2 to incorporate into its RfD calculation for highly volatile chemicals and for subchronic or chronic HRLs.[150]

150. MDH has included an exception of 0.5 for short-duration exposure to non-volatile chemicals. This choice reflects MDH's determination that infants have little exposure to different environments in their first months of life. Thus, the presence of a contaminant in their drinking water would make up a larger relative part of their total exposure to all media. The increase to 0.5 does not extend to contact with volatile chemicals since infants were not more likely to be exposed to them. The selection of 0.5 to reflect exposure of infants to non-volatile chemicals is derived from the EPA decision tree.[151] The RSC approach requires information about the volatility of each chemical for which an HRL is derived. To that end, MDH has classified each chemical's volatility and included it in Part 4717.7860 (proposed), the Health Limits Table.

151. The Chamber of Commerce objected to the selection of the RSC as evidence of the overly conservative assumptions MDH brought to the calculation of the HRLs. MDH responded by restating the information in the SONAR explaining how the RSCs were selected and their derivation through the EPA decision tree process. CropLife America would prefer a methodology that sets ranges for the HRLs since the HRLs are not intended to be a bright line. A range would allow risk managers to make site-specific decisions and eliminate the need for the conservative RSC uncertainty factors.[152]

152. The ALJ concludes that MDH has demonstrated that its definition of Relative Source Contribution and its use in determining the HRL for noncancer effects is necessary and reasonable and takes into account the proportion of total chemical exposure that is likely to be attributed to groundwater.

---

[150] SONAR at 51.

[151] *Id.*

[152] CropLife America Posthearing Comments, Oct. 30, 2008.

4717.7830 For Toxic Effects Other Than Cancer

153. This rule sets forth the formula for calculating the HRL for a toxic effect other than cancer, expressed as micrograms per liter (µg/L). It takes into account the reference dose (RfD), the relative source contribution (RSC), and the intake rate (IR) for a given duration, defined at Minn. R. 4717.7820, subparts 9, item A, and 14 (proposed).

154. As more fully explained in the SONAR, the accepted method for assessing potential toxicity to humans is through controlled laboratory studies using mammals. The testing has two goals: first to identify the hazard or toxic effects caused by the chemical; and second, to evaluate the relationship between the dose and the animal's response. Researchers attempt to determine the lowest dose at which adverse effects related to dosing are observed "LOAEL", and the highest dose at which no adverse effects related to dosing are observed or "NOAEL."

155. For noncancer effects, the selected dose is reduced to account for variability and uncertainty in the human population. In some instances the variability and uncertainty are so great that there is insufficient scientific information available to calculate the reference dose, that is, the milligrams of chemical per kilogram of body weight per day (mg/kg-day) estimated to be without an appreciable risk of adverse effects.[153] Where sufficient information was available, MDH considered the timing and duration of exposure to determine acute, short-term, subchronic, and chronic RfDs.

156. From the characteristics and measurements addressed above, MDH developed algorithms or formulas to determine the noncancer health risk limit, for a given duration ($nHRL_{duration}$,) expressed in units of micrograms of chemical per liter of water (µg/L). Where different, reliable, duration or intake rate information is available for a specific chemical, MDH will vary from the default HRL algorithm, and apply specific RfD, RSC and intake rate (IR) values. Ordinarily, for a given chemical, the shorter-duration RfD values will be higher than longer-duration RfD values because the human body can usually tolerate a higher dose when the duration is short, even if that same dose would be harmful over a longer duration. However, MDH also adjusted the algorithm in instances where the available evidence shows that shorter-duration exposure was sufficient to elicit an adverse effect so that the longer-duration HRL is set equal to the lower, shorter-duration HRL, to insure that the HRL is sufficiently protective.[154]

157. As more fully discussed above, some commenters objected to the definitions of RfD, RSC and Intake Rate used in the formula. Each of those objections has been addressed above.

158. ALJ concludes that MDH has demonstrated that Part 4717.7830 is necessary and reasonable for setting HRLs for toxic effects other than cancer.

[153] SONAR at 3.
[154] SONAR at 34.

4717.7840 For Cancer

159. As discussed above, most carcinogens are typically subject to the conservative assumption that no exposure is without risk. The cancer slope factor measures the increase in risk as dosage increases. MDH also developed an algorithm for the derivation of cancer HRLs, taking into account EPA's age-dependent cancer potency adjustment factors and corresponding intake rates. In this instance, as with the noncancer algorithms, MDH will depart from the default algorithm if sufficient information is available to derive a chemical-specific lifetime adjustment factor. For each chemical, the revised rules include the slope factor (SF), slope factor adjustment, and IR values used.[155]

160. For carcinogens, that is, chemicals that cause cancer, most HRLs employ the "default assumption," that any amount of exposure, no matter how small, potentially carries some risk. Rather than developing an RfD for carcinogens, MDH incorporates its long-standing policy to derive values that limit the excess cancer risk to 1 in 100,000, that is, the level that increases the incidence of cancer by 1 in 100,000 population. "Cancer potency" is expressed as "an upper bound estimate of cases of cancer expected from a dose of one milligram of substance per kilogram of body weight per day (*i.e.* cancer incidence per 1 mg/kg-day)." From these estimates a cancer potency slope, or "slope factor" (SF), can be calculated.[156]

161. In establishing the HRLs, MDH also took into account that cancer incidence from short-term early-life exposure can be similar to chronic adult-only exposure, and can be disproportionate to the duration of the exposure. The Groundwater Protection Act[157] requires MDH to use cancer potency slopes published by EPA when deriving cancer HRLs. In this revision, MDH used the EPA Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (EPA 2005a) to account for the potential for increased cancer potency when exposure occurs early in life. This takes into account potency adjustment factors for three life stages, from birth to 2 years of age and from 2 to 16 years of age, with no adjustment for individuals 16 years of age and older.

162. Objections to the "additional cancer risk level," and the "age-dependent adjustment factor (ADAF)" were discussed above.

163. The American Chemistry Council objects to incorporating any default assumptions and adjustment factors in the methodology and asserts that these additions are not needed or reasonable because they are not based on scientific study. In its view, cancer risk assessment methodology is sufficiently protective and incorporates sufficiently conservative default assumptions to protect the entire population, including subpopulations such as children. Although the American Chemistry Council agrees that such adjustments should be made on a case-by-case

[155] SONAR at 7-9.
[156] SONAR at 4.
[157] Minn. Stat. § 103H.201.

basis when supported by scientific studies, it objects to their inclusion in the methodology absent scientific support.[158]

164. For chemicals with possible carcinogenicity, MDH conducted a case-by-case evaluation of the available data. Where evidence of carcinogenicity was inadequate, MDH derived a noncancer chronic HRL. For chemicals with both cancer and noncancer effect and sufficient toxicity data, cancer and noncancer HRLs were derived.[159]

165. For nonlinear carcinogens, MDH will select an RfD that falls below the threshold for precursor events.[160]

166. The ALJ concludes that MDH has fully considered objections to the proposed rule. The rule as proposed is necessary and reasonable for setting HRLs for cancer.

4717.7850 Use of Maximum Contaminant Levels

167. This rule lists the chemicals for which the federally set maximum contaminant level will be adopted as the HRL. It includes nine chemicals, eight previously adopted as MCLs by publication of notice in the State Register,[161] and one additional chemical, nitrate (as N).

168. Clean Water Action notes that the HRLs can often be *de facto* drinking water benchmarks for Minnesotans whose drinking water comes from wells that are not covered by the drinking water standards. In its opinion, the HRLs should in no instance be less protective than drinking water standards. Thus, Clean Water Action claims the appropriate federal benchmark is the Maximum Contaminant Level Goal (MCLG), "the level of contaminant in drinking water below which there is no known or expected risk to health." Clean Water Action's view is that the MCLG is a better match to the operational definition of the HRLs than the MCL, which takes into account cost and treatment technology factors in addition to health risk.[162] Clean Water Action proposes that the HRL be set at the MCLG for: alachlor, benzene, pentachlorophenol, 1,1,1-trichlorethane and vinyl chloride.[163]

169. MDH responds that it is compelled by statute to use EPA's regulatory standard, and since the MCLG is a goal rather than a regulatory standard, it is not an appropriate basis for adoption as an HRL.[164]

---

[158] American Chemistry Council, Nov. 6, 2008.
[159] SONAR at 5.
[160] SONAR at 59.
[161] 32 SR 43 (July 9, 2007).
[162] Clean Water Action, Posthearing Comments, Oct. 30, 2008, quoting 40 C.F.R. § 141.2.
[163] Clean Water Action, Posthearing Comments, Oct. 30, 2008.
[164] Department Reply Comments, Nov. 6, 2008; *see also* Minn. Laws 2007, Ch. 147, Art. 17, Sec. 2.

170. The ALJ concludes that the rule as proposed is necessary and reasonable.

4717.7860 Health Risk Limits Table

171. This table lists the HRLs derived from the formulas in proposed parts 4717.7830, 4717.7840, and 4717.7850. For each included chemical, the Table specifies the chemical name, its "chemical abstracts services registry number (CAS number)," the year the HRL was established, the volatility classification; any noncancer HRL, any cancer HRL, the RfD and RSC used in the derivation of any noncancer HRL, the slope factor and any ADAF or $AF_{lifetime}$ used in the derivation of any cancer HRL; the intake rate used in the derivation of any noncancer or cancer HRL; and the health endpoints, a general description of the toxic effects for a chemical or group of chemicals.[165]

172. The table includes the MDH-derived HRLs, for those that have been calculated by MDH, and the MCL-based HRLs for the other substances or chemicals included on the chart. As proposed, it includes 22 chemicals or substances, but one, subpart 5, Alachlor ESA, was withdrawn prior to the rule hearing.

Subparts 3 and 4. Acetachlor and Alachlor

173. The Acetochlor Registration Partnership (ARP)[166] objected to the legality of the rulemaking process as a whole, but also objected to the HRLs for acetochlor and alachlor.[167] In particular, it claims that MDH did not follow the representations about methodology set forth in the SONAR and selected toxicity values for these chemicals that differ from the EPA peer-reviewed toxicity values, affecting the calculation of the HRLs. Its comments specify the errors in the MDH calculations and propose what it contends are properly established HRLs.

Acetochlor –

> MDH HRL: 40 µg/L, for acute, short-term, and subchronic exposures and 9 µg/L for chronic exposures.
>
> ARP Proposed HRL: acute, 300 µg/L; short-term, 400 µg/L; subchronic, 300 µg/L; chronic, 90 µg/L.

Alachlor –

> MDH HRL: acute, not determined; short-term, 200 µg/L; subchronic, 30 µg/L; chronic, 5 µg/L.

---

[165] "Health risk index endpoint or health endpoint" is defined at Minn. R. 4717.7820, subp. 12 (proposed).

[166] Dow AgroSciences, LLC, and Monsanto Company, manufacturers of products containing acetochlor and alachlor.

[167] Acetochlor Registration Partnership, Posthearing Comments at 13-29; Posthearing Reply Comments, Nov. 6, 2008.

ARP Proposed HRL: short-term, 3000 µg/L; subchronic, 100 µg/L; chronic, 50 µg/L.

174. ARP pointed out some of the ways that the MDH calculation relied on values that deviated from those used by the EPA. For example MDH used a significantly lower point of departure/NOAEL for proposing acute HRLs for acetochlor: 21.2 mg/kg-day compared to the EPA 150 mg/kg-day. ARP contends that MDH should use the EPA figure to devise the RfD.

175. MDH has fully explained its bases for deviating from some of EPA's published values. It believes that the deviations are necessary to address its statutory directive to address age-appropriate toxicology studies and values, directives that differ from those that guide the EPA.[168]

176. Another significant difference between the two calculations for acetochlor was their differing interpretation of results of a dog study. MDH applied an additional uncertainty factor to the study to account for subchronic to chronic study extrapolation, but ARP contends that no such adjustment to the study is warranted because the dog study was a chronic study. With the application of the uncertainty factor, MDH calculated a chronic RfD/toxicity value of 0.002 mg/kg-day, rather that the 0.02 mg/kg-day value set by the EPA. ARP contends that MDH has offered no scientifically acceptable basis for refusing to accept the EPA value, and MDH's failure to do so demonstrates its inability to evaluate the applicable scientific studies.

177. For alachlor, as with acetochlor, ARP contends that MDH erroneously applied a ten-fold increase in the uncertainty factor and did not apply the correct point of departure/NOAEL set by the EPA. As with acetochlor, ARP contends that the HRL for alachlor devised by MDH reaches an unfounded conclusion about the health risks from potential exposure in groundwater.

178. MDH addressed this concern in its Reply Comments, November 6, 2008. It points out that the one-year dog study was a short-term study, not a chronic study because it did not encompass ten percent or more of the animal's lifetime. It also refers to a statement from the EPA that chronic studies that include prenatal and postnatal exposure into old age are lacking. MDH has explained at length that its mandate differs from the EPA's in that it must consider age-appropriate studies and uncertainty factors. Thus, its choices for values differ from the EPA's.

179. In essence, the ARP challenges the overall policy choice made by MDH and subject to peer review, to apply stricter limitations so that the effect on children may be better incorporated into the HRLs. Although ARP may not agree with this choice, and reasonable minds may differ about its soundness, MDH has demonstrated that the choices are rational, that the choices have been reviewed with outside experts, and that the choices were made to best reflect MDH's understanding of the Legislature's intent.

[168] Department's Posthearing Reply Comments, Nov. 6, 2008, at 12; SONAR at 40ff.

Thus, its decision to incorporate values into the algorithm that vary from those used by the EPA is reasonable.

180. The ALJ concludes that the subparts setting HRLs for acetochlor and alachlor are necessary and reasonable.

Subpart 5. Alachlor ESA

181. ARP also objected to MDH withdrawing its proposed standard for alachlor ESA, a degradate, and applying the values for the parent chemical, alachlor, by application of Minn. R. 4717.7900 (proposed).[169] ARP maintained that the originally proposed HRL was abundantly supported by toxicity data that had been relied upon by MDH for several years and that MDH had previously represented that alachlor ESA is not as toxic as its parent.

182. ARP refutes MDH's representation that there are insufficient toxicity studies to support an HRL. ARP claims that the EPA, European Union and the State of Wisconsin all relied upon a 90-day rat study in which alachlor ESA was administered in drinking water to evaluate safety and establish safe drinking water exposure levels, both the RfD and HRL.[170] Moreover, ARP contends that MDH has relied on that same study for over six years. In its view, MDH's decision at the last minute to withdraw the HRL for alachlor ESA without fully explaining its conclusion that the previously-relied-upon study was unreliable was unjustified and inconsistent with many prior statements by MDH and EPA that alachlor ESA was much less toxic than its parent.[171]

183. ARP also asserts that the proposal to evaluate alachlor ESA using the chronic HRL for the parent alachlor effectively results in a combined uncertainty that far exceeds its stated maximum uncertainty factor of 3,000; ARP asserts that its estimate of the uncertainty factor is 157,000 and 628,000.[172] ARP referred to an EPA toxicity value derived from the same study previously relied upon by MDH that assigned an uncertainty factor of 1,000.[173]

184. Another basis for challenging the use of the HRL for the parent alachlor was the improper application of the alachlor RSC to alachlor ESA. ARP contends that based on data, the worst-case estimate for alachlor ESA is 0.98. This change alone would effectively lower the HRL. ARP requests that MDH follow its "decision tree" for selecting the RSC, and proposes an RSC of 0.8 for alachlor ESA.

185. In ARP's view, rejecting the alachlor ESA database and withdrawing the proposed HRL is arbitrary. Moreover, ARP contends that MDH lacks the authority to set

---

[169] *See also* Test. of Sherman at 38-44.

[170] Acetochlor Registration Partnership Posthearing Comments, Oct. 30, 2008 at 22, citations to studies omitted.

[171] *Id*. at 23-24.

[172] Acetochlor Registration Partnership, Posthearing Comments, Oct, 30, 2008.

[173] *Id.* at 27.

the HRL at the parent level. It also contends that by withdrawing this provision of the proposed rules, the rules are substantially different from the rules as proposed.[174] This view is shared by CropLife America.[175]

186. With its withdrawal of the specific standard for alachlor ESA and reliance on proposed rule 4717.7900, MDH effectively lowered the HRL. ARP contends that the withdrawn HRL would have lowered the HRL five-fold from the previous HRL, from 100 µg/L to 20 µg/L, and by reverting to 4717.7900, the HRL was further reduced four-fold, from 20 µg/L to 5 µg/L for chronic exposure.[176]

187. ARP's proposal is: subchronic HRL, 10,000 µg/L, chronic HRL, 1,000 µg/L, which takes into account the EPA point of departure/NOAEL and additional adjustments.

188. MCEA, IATP and EJA supported the Department's decision to withdraw its proposed HRL for alachlor ESA and to maintain its current practice of adding the concentration of the parent chemical and its degradates and comparing the combined concentration to the HRL for the parent.[177]

189. MDH explained that, since publication of the proposed rule, its staff has identified concerns with the calculation for the alachlor ESA HRL and determined that it was more appropriate to add the concentrations of the degradate to the parent compound and compare the total to the HRL for the parent.[178] Moreover, MDH asserts that it is authorized to withdraw a portion of the rule prior to filing it with the secretary of state,[179] that removal of one proposed HRL from a list of 22 does not significantly modify the proposed rule revisions, and that the notice to the public was clear that the proposed rules could be changed through the process.

190. A modification, including withdrawal of a provision, does not make a rule substantially different unless the change extends beyond the scope of the notice given to the public or raises a subject or has an effect that could not be contemplated.[180] In this instance, the rule set forth HRLs for a number of chemicals, and it could be anticipated that one or more of the HRLs could change based on developments during the rulemaking process. No new subject matter was introduced by virtue of this change, nor was a new class of persons affected, as could be argued if an HRL for an additional chemical were added in the course of the proceeding. The agency explained

---

[174] Acetochlor Registration Partnership, Posthearing Reply Comments, Nov. 6, 2008.

[175] CropLife America Posthearing Comments, Oct. 30, 2008.

[176] *See,* Acetochlor Registration Partnership Posthearing Comments, Oct. 30, 2008, at 22 for chart depicting the reduction in the HRL under successive MDH versions.

[177] *See, e.g.,* MCEA Prehearing Comments, Sept. 17, 2008.

[178] Department Post-Hearing Comments at 4.

[179] *See,* Minn. Stat. § 14.05, subd. 3 ("An agency may withdraw a rule any time before filing it with the secretary of state. An agency may withdraw a portion of a rule unless the remaining rule is substantially different from the rule as published….")

[180] *See*, Minn. Stat. § 14.05, subd. 2; *see also, Chamber of Commerce v. Pollution Control Agency*, 469 N.W.2d 100, 106 (Minn. App. 1991) *rev. denied* (July 24, 1991).

its basis, and, by withdrawing the HRL, reestablished the status quo for this chemical degradate. In its reply comments, MDH addressed this point again, and explained its rationale and its authority for withdrawing the proposed standard.

191. Withdrawing this portion has no effect on the remainder of the rule revisions as proposed and does not constitute a substantial change. If a new HRL for alachlor ESA is subsequently proposed, the public will have a full opportunity to comment.

Subpart 6. Atrazine

192. State Representative Jean Wagenius expressed concern that MDH had not updated the atrazine HRL, even though atrazine is ubiquitous in the environment, and the prior standard was set before atrazine was known to be an endocrine disruptor. In Rep. Wagenius' view, the HRL fails to take into account the legislative directive to include a reasonable margin of safety to protect infants, children and adults, taking into account a range of health outcomes.[181]

193. MDH replied that atrazine was evaluated in 1993/1994 and the calculated HRL value was 20 ppb. As one of the most commonly detected chemicals in Minnesota groundwater, MDH adopted the EPA MCL of 3 ppb as the HRL until it can derive a new value. It is currently reviewing available scientific information for atrazine and intends to derive HRL values for future rule revision. It will also complete scientific review of atrazine degradates.[182]

194. Syngenta has also criticized the atrazine HRL value. It asserts that the HRL is not based on a current reference dose, cancer classification or risk assessment, and that the allocation of RSC should be reexamined.[183] MDH responded that it has not had the opportunity to conduct a review of atrazine and has adopted the MCL until it has the opportunity to do so.[184]

195. The ALJ concludes that MDH has demonstrated the need for and reasonableness of this subpart.

Subpart 14. Nitrates

196. MCEA, IATP and EJA objected to MDH's selected HRL for Nitrates, asserting that the HRL is based on an out-dated federal standard. In response, MDH reiterates that it will review nitrates for future HRL revision, but disagrees that the proposed standard does not adequately protect human health. The HRL is based on a human epidemiologic study of the most sensitive subpopulation. MDH notes that no

[181] Jean Wagenius, State Representative, Oct. 30, 2008, via e-mail.
[182] Department Reply Comments, Nov. 6, 2008, at 3.
[183] Syngenta Posthearing Comments, Oct. 30, 2008.
[184] Department's Posthearing Comments, Oct. 30, 2008, at 3-4.

adverse effects were noted at the proposed HRL, water concentration of 10,000 µg/L or less. Nitrate is among the most commonly detected groundwater contaminants.

197. Including a standard in this rule revision is consistent with the 2007 legislation directing MDH to set standards for commonly occurring contaminants. MDH has demonstrated that its standard for nitrates is necessary and reasonable.

Subparts 16 and 17. Perfluoroctanane sulfonate (PFOS) and Perfluorooctanoate (PFOA)

198. 3M has objected to two specific aspects of the HRL for PFOS and PFOA: the calculation of the RfD, and the use of the default relative source contribution (RSC) of 20 percent.

199. 3M asserts that MDH has made an error in the calculation of the Reference Dose (RfD) for PFOS and PFOA.[185] Correcting the error would not change the proposed HRL for PFOA but would raise the parts per billion from 0.3 to 0.4 for PFOS. 3M has two objections to MDH's determination of the RfD. First, it asserts that by including the Human Equivalent Dose (HED), MDH has made an adjustment in the RfD that it did not make for any other chemical, that MDH has not defined HED, and that MDH has not articulated its basis for applying the HED to these chemicals. 3M asserts that, in the SONAR, MDH has stated that EPA has only applied HED conversions to convert from inhalation doses across species, not to calculate oral toxicity values. If MDH intends to use an HED adjustment in its RfD, 3M contends that the rule should specify when and how the approach will be used.

200. Second, 3M asserts that MDH has used the wrong value of the human half-life of PFOS and PFOA, applying an arithmetic mean rather than geometric mean. This change affects the HED calculation and also the intake rate. As stated above, correcting the calculations will not alter the HRL for PFOA but would increase the HRL for PFOS to 0.4 parts per billion (ppb).

201. 3M's second significant area of concern is that MDH used a default value of 20% to represent the percentage of exposure to PFOA and PFOS that comes from drinking water, the RSC. 3M references current data showing that drinking water is the predominant source of exposure for these materials. Using the RSC based on the available data would increase the HRLs for each of the two chemicals by a factor of two to four. 3M proposes that MDH select a data-based RSC of 50% to 80% to replace the default 20% included in the HRL calculation.[186]

202. In addition to its concerns about the HRL calculations, 3M also raises questions about some of the effects listed as endpoints for PFOS and PFOA on the Health Risk Limits Table.[187] In particular, it objects to the listing of thyroid effects as

[185] 3M Posthearing Comments, Oct. 30, 2008 at 2-8.
[186] 3M Posthearing Comments, Oct. 30, 2008, at 8-11.
[187] 3M Posthearing Comments, Oct. 30, 2008, at 11-12.

contrary to the published literature for PFOS and requests that the reference to thyroid effects be deleted from the table. 3M is also concerned that MDH considered increased liver weight in monkeys in determining adverse effects of PFOA. 3M contends that there is insufficient evidence that this is an adverse effect and that it should not be listed as one. 3M requests that MDH clarify that it is taking a precautionary, conservative approach by referring to this possible adverse effect.

203. 3M agrees that it is important to set benchmarks to address the level of these substances in the drinking water and expressed its appreciation for MDH's efforts to match assumed drinking water intake rates to specific life stages. However, it believes that MDH's intake rates in the HRL methodology are unrealistic generally and as applied to PFOS and PFOA.[188] Specifically, it contends that using intake rates representative of the 95th percentile of the population is unreasonably conservative. In its view, a value at the 90th percentile is sufficiently conservative because of the other conservative choices in the HRL methodology. It refers to studies done on blood levels of PFOS and PFOA as evidence that the methodology is too conservative.

204. Under the methodology as applied to PFOS, and assuming consumption at the 95th percentile over the first 27 years of life, the intake rate would be 0.049 liters of water per kilogram of body weight per day over the time period. The intake rate for an adult weighing 70 kilograms or 154 pounds would be 3.71 liters or 0.98 gallons of tap water per day every day. In 3M's view, an HRL set at this level is unrealistic, and the other conservative components of the methodology, including the uncertainty factors, coupled with the 90th percentile of intake, would be sufficiently protective.

205. MDH has given a detailed response to 3M's objections.[189] As explained above, MDH did not lay out each parameter used in its calculation of the RfDs, but explained the process and published the RfD so that its calculation could be reviewed.[190] It also reiterates that chemical-specific information is available for PFOS and PFOA and will be used in the HED calculations. MDH did note that it had identified an error in its determination of the half-life values for PFOS and PFOA, but that the difference did not change the value of the RfD or the HRL for PFOS.

206. MDH also noted that the identified liver effects in monkeys are adverse effects, and that the determination is supported by observations in other species.

207. MDH reviewed its determination of the RSC in light of 3M's concerns, but determined that its selection of a default value of 0.2 was appropriate. It also reviewed 3M's objections to listing thyroid effects for PFOS, but explained that, based on the studies it had reviewed, including thyroid as a health endpoint was appropriate.

208. The ALJ concludes that MDH has demonstrated that the HRLs for PFOS and PFOA are necessary and reasonable.

---

[188] 3M Posthearing Comments, Oct. 30, 2008, at 12-13.

[189] Department's Posthearing Reply Comments, Nov. 6, 2008, at 7-8.

[190] *See also* SONAR at 30-31, and EPA documents cited therein.

Subpart 24. Vinyl Chloride

209. Darlene A. Konz expressed her objection to the proposed HRL of 0.2 µg/L for vinyl chloride and her preference for the draft value of 0.08 µg/L proposed in 2004.[191] MCEA also objected to the change from the proposed 2004 HRL.[192] Clean Water Action proposed that the HRL should be set at the MCLG of 0.0 ppb. MDH explained that it had consulted with the EPA and relied upon additional information that the initially proposed value inappropriately combined lifetime cancer potency and an additional adjustment for a child's intake rate. Also, as discussed above, the MCLG is a goal and not an EPA standard.

210. MDH has demonstrated that the proposed subpart for vinyl chloride is necessary and reasonable.

Subpart 25. Transition

211. At the time of the hearing, the Department proposed to add the following new subpart to the proposed rules to address the transition period of the HRL values:

> The health risk limits established for the specific chemicals in this part supersede the health risk limits for those chemicals specified in part 4717.7500. For chemicals not included in this table, the health risk limits established in 4717.7500 remain in place.

212. This change is responsive to some comments that the relationship between the existing rule, Part 4717.7500, and values sent in Part 4717.7860 (proposed) were not clear.[193] The addition of this subpart clarifies the relationship, and there were no objections to adding this clarification to the rules.

213. The ALJ concludes that the addition of this subpart is necessary and reasonable and is not a substantial change from the rules as originally published in the State Register.

4717.7870 Evaluating Concurrent Exposures to Multiple Chemicals

214. The purpose of this rule is to consider the risk presented by multiple chemicals in the groundwater. This rule clarifies that the risk for effects other than cancer will be evaluated as specified in part 4717.7880, and cancer risks as specified in part 4717.7890. If a chemical causes both cancer and effects other than cancer, the chemical must be included in both evaluations. This rule also sets the applicable HRL for multiple chemical risks: "When the multiple chemical health risk index is greater than one, the multiple chemical health risk limit has been exceeded." There were no objections to this proposed rule.

---

[191] Darlene A. Konz, prehearing email comment, Sept. 21, 2008.

[192] MCEA Prehearing Comments, Sept. 17,2008; Test. of Samuel Yamin, T. 52.

[193] *See, e.g.,* Pollution Control Agency, Oct. 10, 2008.

215. The ALJ concludes that MDH has shown that it is necessary and reasonable to explain the effect of exposure to multiple chemicals in groundwater.

4717.7880 Multiple Chemical Health Risk Limits: Noncancer

216. The purpose of this rule is to establish the process for evaluating the noncancer risk of multiple contaminants in groundwater. First, chemicals are grouped for each "health endpoint," as defined in Part 4717.7820, subp. 12 (proposed), and set forth for each chemical in Part 4717.7860 (proposed). Then a noncancer index is calculated for each group of two or more chemicals with a common duration period. This sums the micrograms per liter for the grouped chemicals. There were no objections to the proposed rule.

217. The ALJ concludes that MDH has demonstrated the need for and reasonableness of the proposed rule.

4717.7890 Multiple Chemical Health Risk Limits: Cancer

218. The purpose of this rule is to establish the process for evaluating the cancer risk of multiple contaminants in the groundwater. It includes the equation to sum the HRLs for each of the individual contaminants. There were no objections to the proposed rule.

219. The ALJ concludes that MDH has demonstrated the need for and reasonableness of the proposed rule.

4717.7900 Chemical Breakdown Products

220. As the rule states, when chemical breakdown products (degradates) are present in groundwater, it is necessary to assess the risk of those products. In this rule, MDH proposes that if there is no HRL for the degradate, the health risk limit specified for the parent chemical in Minn. R. 4717.7860 (proposed) will be the HRL for the degradate. When a parent and one or more degradates or several degradates are present, the process for evaluating multiple chemical HRLs, parts 4717.7880 and 4717.7890 (proposed) will apply. By withdrawing the proposed HRL for alachlor ESA, a degradate of alachlor, MDH explains that the HRL will be set by application of this proposed rule.

221. The ARP challenges the statutory authority for this rule, as well as its reasonableness.[194] It contends that the statutory authority for the rules, Minn. Stat. § 103H.201, authorizes the promulgation of HRLs for substances degrading the groundwater using two methods. In this instance, MDH is relying on the HRL for a parent chemical when a specific HRL has not been adopted for a degradate that is detected in the groundwater. ARP characterizes this as a default assumption, without

[194] Acetochlor Registration Partnership Posthearing Comments, Oct. 30, 2008, and Reply Comments, Nov. 6, 2008.

any basis in the scientific research, and contends that nothing in the statute would allow this approach.

222. Moreover, ARP argues that the proposed rule is impermissibly vague because, by its terms, it applies when there is an "absence or paucity of toxicity information on the chemical breakdown product," without setting forth a standard by which MDH will make that determination. As an example, ARP objects to the application of the rule to alachlor ESA because, it argues, scientifically-based standards for the degradate have been set and relied upon in other jurisdictions, and MDH has failed to explain why the available information is inadequate. Thus, the agency's decision is left to its whim and is necessarily arbitrary and unreasonable.[195]

223. Syngenta submitted comments about the application of this rule to atrazine.[196] It contends that MDH has adopted the MCL-based HCL for atrazine but has identified three chlorinated atrazine degradates to be included as breakdown products in the 3 parts per billion (ppb) HRL for atrazine. Syngenta recommends that MDH acknowledge that sufficient toxicity data and human health-based drinking water values exist for atrazine and its chloro degradates, that the provisions of Part 4717.7900 (proposed) and Part 4717.7880 (proposed) should not apply, and that MDH adopt an EPA standard of 12.5 ppb as the groundwater HRL inclusive of atrazine and its chloro degradates deethylatrazine (DEA), deisopropylatrazine (DIA) and diaminochloroatrazine (DACT). Syngenta asserts that this is a very conservative standard. Moreover, Syngenta requests that any future MDH calculation of an HRL for atrazine and its degradates use a specific relative source contribution (RSC).

224. MDH points out that it has the authority to regulate substances degrading the state's groundwater and that the statute makes no distinction between parent compounds and degradates. Moreover, either toxicity data is not available for most degradates, or the data does not meet peer review standards. MDH contends that using the data for the parent compound is sound when the values for the degradate cannot be calculated. Products of degradation may be either more or less toxic than the parent. Thus, MDH contends that it is reasonable to apply the toxicity information and analyses for the parent to evaluate the toxicity of the degradate. This approach is consistent with MDH's advice to risk managers to use the parent HRL when no separate HRL is available for the degradate, an approach that is followed by the EPA and other state agencies. Thus, the rule makes explicit a customary practice.[197]

225. It is appropriate to state in rule the approach that will be applied to degradates when no separate HRL has been set, and the proposed rule is consistent with the statutory directive to address chemicals that are degrading groundwater. MDH has demonstrated that its proposed rule is necessary and reasonable. Since

---

[195] Acetochlor Registration Partnership Posthearing Comments, Oct. 30, 2008, at 8-9, citing *inter alia, Manufactured Housing Inst. v. Pettersen*, 347 N.W.2d 238, 244 (Minn. 1984).

[196] Ronald W. Williams, Stewardship Manager, Syngenta, Posthearing Comments, Oct. 30, 2008.

[197] SONAR at 110; Department's Posthearing Reply Comments, Nov. 6, 2008, at 11, citing Minn. Stat. § 103H.201, subd. 1.

degradates are among the most commonly detected contaminants in state groundwater,[198] MDH has the responsibility and authority to set appropriate limits.

Repealer

226. MDH proposes repeal of several rule provisions that will be replaced by the proposed rules. Prior to the hearing, the Department identified a typographical error in the Repealer. The Department notes that the reference to 4717.4200 should be changed to 4717.7200.

227. This correction is needed and reasonable and does not make the Repealer substantially different from the rules as originally published in the State Register.

228. Syngenta objected to the repeal of Minn. R. 4717.7800. It asserts that the provision "was designed to protect the public and to insure that MDH derived HRLs are based on the most current and up to date scientific assessments."[199] The rule specifically required MDH to take action to maintain up-to-date HRLs, and utilize the most current scientific risk assessments in the development of HRLs. In its view, removal of these assurances will adversely affect Minnesota public health. The Acetachlor Registration Partnership and CropLife America also objected to the repeal because this rule ensures that the HRLs will be kept current.

229. MDH did not specifically respond to this objection. However, it is obvious that the language of Part 4717.7800 is inconsistent with the proposed rules in several significant ways. First, it addresses revisions to two other repealed rules. Second, it includes methods and definitions that have been replaced in the proposed rules. Third, it directs changes in the HRLs to be issued in the State Register rather than through rulemaking as the statutes currently require. There are additional inconsistencies that support MDH's determination that this rule should be repealed.

230. ALJ concludes that the repeal of Minn. R. 4717.7800 is necessary and reasonable.

Based on the Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Department gave proper notice in this matter. The Department has fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule, except as noted in Findings 25-27 and 62.

[198] Alachlor ESA, and deethylatrazine and deisoproplyatrazine (atrazine degradates). SONAR at 13; Department's Posthearing Reply Comments, Nov. 6, 2008, at 13.
[199] Ronald W. Williams, Stewardship Manager, Syngenta, Posthearing Comments, Oct. 30, 2008.

2. The Department has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1; 14.15, subd. 3; and 14.50 (i) and (ii).

3. The Department has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 4; and 14.50 (iii), except as noted in Finding 146.

4. The additions and amendments to the proposed rules suggested by the Department after publication of the proposed rules in the State Register are not substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.05, subd. 2, and 14.15, subd. 3.

5. The ALJ has suggested actions to correct the defects cited in Conclusions 1 and 3, as noted in Findings 62 and 146.

6. Due to Conclusions 1, 3 and 5, this Report has been submitted to the Chief ALJ for his approval pursuant to Minn. Stat. § 14.15, subd. 3.

7. Any Findings that might properly be termed Conclusions and any Conclusions that might properly be termed Findings are hereby adopted as such.

8. A Finding or Conclusion of need and reasonableness with regard to any particular rule subsection does not preclude and should not discourage the Department from further modification of the proposed rules based upon this Report and an examination of the public comments, provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based on the Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS RECOMMENDED that the proposed rules, as modified, be adopted, except where otherwise noted above.

Dated: December 11, 2008.

/s/ Beverly Jones Heydinger
BEVERLY JONES HEYDINGER
Administrative Law Judge

Recorded: Reported by Kirby Kennedy & Associates
Transcript (one volume)